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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61F 2/06	A2	(11) International Publication Number: WO 00/44309 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/US00/02582 (22) International Filing Date: 1 February 2000 (01.02.00) (30) Priority Data: 60/118,185 1 February 1999 (01.02.99) US 60/125,192 18 March 1999 (18.03.99) US (71) Applicant: BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [US/US]; 201 West. 7th Street, Austin, TX 78701 (US). (72) Inventors: HYODOH, Hideki; Kawachi, Tochigi (JP). KONYA, Andras; 550 N. Braeswood #256, Houston, TX 77096 (US). WRIGHT, Kenneth, C.; 1802 Haver, Houston, TX 77006-2414 (US). (74) Agent: GARRETT, Mark, T.; Fulbright & Jaworski, Suite 2400, 600 Congress Avenue, Austin, TX 78701 (US).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: WOVEN BIFURCATED AND TRIFURCATED STENTS AND METHODS FOR MAKING THE SAME (57) Abstract Bifurcated and trifurcated woven stents for insertion and delivery into a variety of anatomical structures, including the aortic-iliac bifurcation, the superior vena cava junction, and the inferior vena cava junction. The bifurcated stents includes a first leg formed from a first plurality of wires, a second leg formed from a second plurality of wires, and a common body formed from the first and second pluralities of wires. The wires may be nitinol. Biodegradable filaments may also be utilized. The angles created between the crossed wires is preferably obtuse. A variety of delivery devices formed from differently-sized tubes, portions of which may operate co-axially with each other, are also included. The bifurcated stents may operate co-axially with each other, are also included. The bifurcated stents may be formed from as few as two wires. The stents may be formed using plain weaving effected either by hand or by machine.		

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APPLICATION FOR UNITED STATES LETTERS PATENT

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for

WOVEN BIFURCATED AND TRIFURCATED STENTS

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AND METHODS FOR MAKING THE SAME

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BACKGROUND OF THE INVENTION

The present application claims priority to U.S. Provisional Patent Application Serial No. 60/118,185 filed February 1, 1999 and U.S. Provisional Patent Application Serial No. 60/125,192 filed March 18, 1999. The entire texts of the above-referenced disclosures are specifically incorporated by reference herein without disclaimer.

1. Field of the Invention

The present invention relates to a self-expanding bifurcated stent and apparatus and methods for inserting the same into a bifurcated anatomical structure.

2. Description of Related Art

Numerous studies have reported the use of metallic stents for the treatment of stenotic lesions occurring in tubular anatomic structures (Wallace *et al.*, 1986; Palmaz, 1988; Milroy *et al.*, 1989; Günther *et al.*, 1989; Riving *et al.*, 1989). Placement of these stents is less invasive than surgical procedures and the stents provide more luminal space than most solid tube devices. Therefore, metallic stents have been widely used for treatment of stenotic diseases in humans. Several different types of stents have been used to treat both straight and curved lesions (Gillams *et al.*, 1990).

The use of straight, cylindrical stents has some limitations. One major limitation is the treatment of lesions occurring at a bifurcation (Nashef *et al.*, 1992). Many methods for stenting these lesions with straight stents have been described including side-by-side insertion (Morita, 1997), pull-through technique (Morita, 1987), creation of a T-configuration (Morita, 1987), Y-stenting (Fort, 1996), and V-stent insertion (Schampaert, 1996). However, no ideal method has been established because only straight stents with a cylindrical configuration are commercially available.

Additionally, the use of such a stent to treat disease at or near a branch of a bifurcation of a blood vessel runs the risk of compromising the degree of patency of the primary vessel and/or its branches of the bifurcation. This may occur as a result of

5
1 several problems such as displacing diseased tissues, vessel spasm, dissection with or
2 without intimal flaps, thrombosis, and embolism. For example, a bifurcated vascular or
3 non-vascular lesion can be bridged by two straight cylindrical stents arranged in a Y-
10 4 shape. One of the stents is longer forming one leg and the common trunk of the Y, while
5 another short stent is attached to the longer one in an end-to-side fashion to form the other
6 leg of the Y-shape. In this situation, the patency of the shorter leg is threatened by the
7 fact that at the site of the attachment of the two stents the stent mesh of the longer stent
15 8 interferes with the free flow of blood, bile, etc. Such an attachment has a high propensity
9 for thrombosis and consequent occlusion in the vasculature, stenosis, bile congestion,
10 inflammation, and eventually occlusion in the biliary tree. In the tracheobronchial
20 11 system, mucus deposition will readily result in serious coughing, infection, and exclusion
12 of the affected part of the lung from gas-exchange.

13 14 SUMMARY OF THE INVENTION

25
15 In one respect, the invention is a device suitable for implantation into an
16 anatomical structure that includes, but is not limited to, a first plurality of wires that
30 17 define a first leg, which has a first distal portion; a second plurality of wires that define a
18 second leg, which has a second distal portion; and a common body that has a distal end
19 and a proximal portion. The common body is formed from at least the first and second
20 pluralities of wires. The proximal portion of the common body is adjacent to the distal
35 21 portions of both legs, and both ends of at least one wire from one of the pluralities is
22 located proximate (near) the distal end of the common body.

40 23 The wires in the first and second pluralities may be made from nitinol. The wires
24 in the first and second pluralities may be made from FePt, FePd or FeNiCoTi. The wires
25 in the first and second pluralities may also be made from FeNiC, FeMnSi or
26 FeMnSiCrNi. The wires in the first and second pluralities may each have a diameter
45 27 ranging in size from about 0.006 inches to about 0.014 inches. The first plurality of wires
28 may include at least 6 wires. Both the legs and the common body may have tubular
29 shapes with substantially uniform diameters. At least one of the legs of the device may

5 1 be hand woven. At least one of the legs of the device may be machine woven. The
2 2 device may also include a graft material attached to at least the common body. The graft
3 3 material may be made from woven Dacron. The graft material may be made from
10 4 polyurethane. The graft material may also be made from PTFE.

5 5 In another respect, the invention is a stent that includes, but is not limited to, a
6 6 first plurality of flexible tubular strands woven to form a first leg that has a first distal
15 7 portion. The flexible tubular strands in the first plurality cross each other to form a first
8 8 plurality of angles. At least one of the angles in the first plurality of angles is obtuse.
9 9 The stent also includes, but is not limited to, a second plurality of flexible tubular strands
10 10 woven to form a second leg that has a second distal portion. The flexible tubular strands
20 11 in the second plurality cross each other to form a second plurality of angles. At least one
12 12 of the angles in the second plurality of angles is obtuse. The stent also includes, but is not
13 13 limited to, a common body that has a common portion. The common body is formed
25 14 from at least the first and second pluralities of flexible tubular strands. The common
15 15 portion of the common body is adjacent to the distal portions of the first and second legs.

16 16 The flexible tubular strands in the first and second pluralities may be made from
30 17 nitinol or biodegradable filaments.

18 18 In another respect, the invention is a stent that includes, but is not limited to, a
19 19 first plurality of wires that define a first leg, which has a first distal portion. The stent
35 20 also includes, but is not limited to, a second plurality of wires that define a second leg,
21 21 which has a second distal portion. The stent also includes, but is not limited to, a third
22 22 plurality of wires that define a third leg, which has a third distal portion. The stent also
40 23 includes, but is not limited to, a common body that has a proximal portion and a distal
24 24 end. The common body is formed from at least the first, second and third pluralities of
25 25 wires. The proximal portion of the common body is adjacent to the distal portions of
26 26 each of the three legs.

45 27 The wires in each of the pluralities may be made from nitinol. The first plurality
28 28 of wires may include at least 5 wires. Each of the legs and the common body may have

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1 tubular shapes with substantially uniform diameters. At least one of the legs may be hand
2 woven or machine woven. The stent may also include a graft material that is attached to
3 at least the common body. The graft material may be made from woven Dacron. The
10 4 graft material may be made from polyurethane.

5 In another respect, the invention is a stent that includes, but is not limited to, a
6 first leg that has a first axis and a first end. The first leg includes, but is not limited to, a
15 7 first wire that has a first segment and a second segment, which are separated by a bend in
8 the first wire located proximate (near) the first end of the first leg. The first segment
9 extends helically in a first direction around the first axis away from the first end of the
20 10 first leg, and the second segment extends helically in a second direction around the first
11 axis away from the first end of the first leg. The segments cross each other in a first
12 plurality of locations. The stent also includes, but is not limited to, a second leg that has a
13 second axis and a second end. The second leg includes, but is not limited to, a second
25 14 wire that has a first segment and a second segment, which are separated by a bend in the
15 second wire located proximate (near) the second end of the second leg. The first segment
16 extends helically in a first direction around the second axis away from the second end of
30 17 the second leg, and the second segment extends helically in a second direction around the
18 second axis away from the second end of the second leg. The segments cross each other
19 in a second plurality of locations. The stent also includes, but is not limited to, a common
20 body that is formed from at least one end of each of the wires.

35 21 The first segment of the first wire may be positioned farther from the first axis
22 than the second segment of the first wire at at least one location among the first plurality
23 of locations. The first segment of the first wire may be positioned farther from the first
40 24 axis than the second segment of the first wire at each location of the first plurality of
25 locations. The first and second wires may be made from nitinol.

45 26 In another respect, the invention is a method of creating a device suitable for
27 implantation into an anatomical structure. The device may have a first leg, a second leg,
28 and a common body. Each leg may have an end and a distal portion. The common body
29 may have a proximal portion and a distal end. The method includes, but is not limited to,

5 1 bending the wires in a first plurality of wires to create first bent portions in the wires. The
2 2 first bent portions are arranged to define the end of the first leg. Each wire in the first
3 3 plurality has two ends. The method also includes, but is not limited to, bending the wires
10 4 in a second plurality of wires to create second bent portions in the wires. The second bent
5 5 portions are arranged to define the end of the second leg. Each wire in the second
6 6 plurality has two ends. The method also includes, but is not limited to, weaving the ends
15 7 of the wires in the first plurality to create the first leg; weaving the ends of the wires in
8 8 the second plurality to create the second leg; and weaving the ends of the wires in both
9 9 pluralities to create the common body and the device. The proximal portion of the
10 10 common body is adjacent to the distal portions of both legs.

20 11 The first bent portions may be bends or loops. The wires in the first and second
12 12 pluralities may be made from nitinol. The wires in the first and second pluralities may
13 13 each have a diameter ranging in size from about 0.006 inches to about 0.014 inches. The
25 14 step of weaving the ends of the wires in the first plurality may be performed by hand or
15 15 by machine.

30 16 In another respect, the invention is a method of creating a stent, which may have a
17 17 first leg, a second leg, and a common body. Each leg may have an end and a distal
18 18 portion, and the common body may have a proximal portion and a distal end. The method
19 19 includes, but is not limited to, providing a weaving system that includes, but is not
35 20 limited to, a first template that has first template projections, a proximal end and a distal
21 21 end. The method also includes, but is not limited to, bending the wires in a first plurality
22 22 of wires around the first template projections to create first bent portions in the wires.
23 23 The first bent portions are arranged to define the end of the first leg. Each wire in the
40 24 first plurality has two ends. The method also includes, but is not limited to, bending the
25 25 wires in a second plurality of wires to create second bent portions in the wires. The
26 26 second bent portions are arranged to define the end of the second leg. Each wire in the
45 27 second plurality has two ends. The method also includes, but is not limited to, weaving
28 28 the ends of the wires in the first plurality to create the first leg; weaving the ends of the
29 29 wires in the second plurality to create the second leg; and weaving the ends of the wires

1 in both pluralities to create the common body and the stent. The proximal portion of the
2 common body is adjacent to the distal portions of both legs.

3 The weaving system may also include, but is not limited to, a second template that
4 has second template projections, a proximal end and a distal end; and a third template that
5 a proximal end and a distal end. The distal ends of the first and second templates may be
6 configured to be placed within the proximal end of the third template. The step of
7 bending the wires in the second plurality of wires may include bending the wires in the
8 second plurality of wires around the second template projections to create second bent
9 portions in the wires. The step of weaving the ends of the wires in both pluralities may
10 include weaving the ends of the wires in both pluralities around the third template to
11 create the common body and the stent.

12 The weaving system may also include, but is not limited to, a second template
13 having a proximal end, a distal end, second template projections arranged around the
14 second template proximate (near) the proximal end thereof, and an opening positioned
15 between the proximal and distal ends of the second template. The opening is configured
16 to accept the distal end of the first template. The step of bending the wires in the second
17 plurality of wires may include bending the wires in the second plurality of wires around
18 the second template projections to create second bent portions in the wires. The step of
19 weaving the ends of the wires in the second plurality may include weaving the ends of the
20 wires in the second plurality around the portion of the second template located proximally
21 of the opening therein to create the second leg. The step of weaving the ends of the wires
22 in both pluralities may include weaving the ends of the wires in both pluralities around
23 the portion of the second template located distally of the opening therein to create the
24 common body and the stent.

25 The first template projections may be pins, which may be attached to a ring
26 engaged with the first template. The method may also include, but is not limited to,
27 securing the wires in the first plurality of wires to the first template. The method may
28 also include, but is not limited to, forming closed structures with the ends of the wires in
29 both pluralities. The closed structures may be arranged to define the distal end of the

1 common body. The method may also include, but is not limited to, heating the stent and
2 the first template.

3 BRIEF DESCRIPTION OF THE DRAWINGS

4 The following drawings form part of the present specification and are included to
5 further demonstrate certain aspects of the present invention. The invention may be better
6 understood by reference to one or more of these drawings in combination with the
7 description of illustrative embodiments presented herein.

8 FIG. 1A is a perspective view of a bifurcated stent according to one embodiment
9 of the present invention.

10 FIG. 1B is a side view of the arrangement of wires in a plain weave according to
11 one embodiment of the present invention.

12 FIG. 1C is a front view of a bifurcated stent formed from two wires according to
13 one embodiment of the present invention.

14 FIG. 2 is a front view of a proximal portion of a delivery system according to one
15 embodiment of the present invention.

16 FIG. 3 is a perspective view of a delivery system for a bifurcated stent according
17 to one embodiment of the present invention.

18 FIG. 4 is a perspective view of a portion of a delivery system according to one
19 embodiment of the present invention.

20 FIG. 5 is a perspective view of a stretched bifurcated stent on a delivery system
21 according to one embodiment of the present invention.

22 FIG. 6 is a perspective view of a delivery system according to one embodiment of
23 the present invention.

5
1 **FIG. 7** is a front view of a trifurcated stent according to one embodiment of the
2 present invention.

10 3 **FIG. 8** is a front view of a trifurcated stent in a delivered position according to
4 one embodiment of the present invention.

15 5 **FIG. 9** is a front view of a bifurcated stent according to one embodiment of the
6 present invention.

7 **FIG. 10** is a front view of a bifurcated stent in a delivered position according to
8 one embodiment of the present invention.

20 9 **FIGS. 11-19** show stages in a hand weaving method according to one
10 embodiment of the present invention.

25 11 **FIG. 20** depicts two bifurcated stents delivered into the aortic arch according to
12 one embodiment of the present invention.

30 13 **FIG. 21** depicts three bifurcated stents delivered into the aortic arch according to
14 one embodiment of the present invention.

15 **FIG. 22** depicts a partially-covered bifurcated stent delivered into the aortic arch
16 and sealing an aneurysmal sac according to one embodiment of the present invention.

35 17 **FIG. 23** is a perspective view of the templates for a bifurcated stent according to
18 one embodiment of the present invention.

40 19 **FIG. 24** is a perspective view of the templates for a bifurcated stent in an
20 assembled position according to one embodiment of the present invention.

45 21 **FIGS. 25A-C** is a perspective view of wires woven on leg templates that are then
22 attached to a common body template on which the weaving continues according to one
23 embodiment of the present invention.

5
1 **FIG. 26** is a perspective view of a bifurcated stent woven on an assembled
2 bifurcated template according to one embodiment of the present invention.

10
3 **FIG. 27A** is a perspective view of templates arranged for use in forming a
4 trifurcated stent according to one embodiment of the present invention.

5 **FIG. 27B** is a perspective view of templates arranged for use in forming a
15 6 trifurcated stent and wires woven thereon according to one embodiment of the present
7 invention.

8 **FIG. 28** is a perspective view of a biodegradable leg with a reinforcing wire
20 9 according to one embodiment of the present invention.

10 **FIG. 29** is a perspective view of a biodegradable leg with a reinforcing wire
11 according to a second embodiment of the present invention.

25 12 **FIG. 30** is a front view of an abdominal aortic aneurysm being treated by
13 transcatheter embolization according to one embodiment of the present invention.

30 14 **FIG. 31** is perspective view of a template with longitudinal tabs around which
15 wires are bent according to one embodiment of the present invention.

16 **FIG. 32A** is an enlarged perspective view of the longitudinal tab and bent wire
35 17 depicted in **FIG. 31** according to one embodiment of the present invention.

18 **FIG. 32B** is an enlarged perspective view of a longitudinal tab depicted in
19 **FIG. 31** around which a wire is bent to form a loop according to one embodiment of the
40 20 present invention.

21 **FIG. 33** is a perspective view of a wire bent around a longitudinal tab and
22 wrapped around a pair of bobbins according to one embodiment of the present invention.

45 23 **FIG. 34** is a top view of upper and lower weaving plates provided with bobbins
24 according to one embodiment of the present invention.

5
1 **FIG. 35** is a cross-sectional front view of upper and lower weaving plates
2 arranged on different planes around a template and provided with bobbins and wires
3 according to one embodiment of the present invention.

10
4 **FIG. 36A** is a top view of upper and lower weaving plates provided with bobbins
5 and wires and arranged around a template, and illustrates the first crossing of the wires
6 according to one embodiment of the present invention.

15
7 **FIG. 36B** is a front view of a small caliber loop formed by bending a wire
8 according to one embodiment of the present invention.

20
9 **FIG. 37A** is a top view of upper and lower weaving plates provided with bobbins
10 and wires and arranged around a template, and illustrates the first crossing of the wires
11 according to another embodiment of the present invention.

25
12 **FIG. 37B** is a front view of a bend formed by bending a wire according to one
13 embodiment of the present invention.

30
14 **FIG. 38** is a perspective view of upper and lower weaving plates provided with
15 bobbins and arranged around a template such that the surfaces of the weaving plates from
16 which the bobbin rods extend face each other according to one embodiment of the present
17 invention.

35
18 **FIG. 39** is a perspective view of upper and lower weaving plates provided with
19 bobbins and wires and arranged around a template such that the surfaces of the weaving
20 plates from which the bobbin rods extend face each other according to one embodiment
21 of the present invention.

40
22 **FIG. 40** is a front view of two bifurcated stents placed in side-by-side relationship
23 with each other in the aorta according to one embodiment of the present invention.

45
24 **FIG. 41A** is a perspective, partial cross-sectional view of a tool for twisting the
25 wire ends of a woven stent according to one embodiment of the present invention.

5
1 **FIG. 41B** is a cross-sectional view of the jaws and outer housing of the tool
2 illustrated in **FIG. 41A**.

10
3 **FIG. 42A** is a perspective view of a portion of the common body of a stent woven
4 around a template having transverse tabs according to one embodiment of the present
5 invention.

15
6 **FIG. 42B** is an enlarged perspective view of one of the transverse tabs and twisted
7 wire ends depicted in **FIG. 42A** according to one embodiment of the present invention.

8 **FIG. 43** is a perspective view of a template around which a ring having finish pins
20 9 has been threadably engaged according to one embodiment of the present invention.

10 **FIG. 44** is a perspective view of a template having finish holes through which
11 finish pins may be placed according to one embodiment of the present invention.

25
12 **FIG. 45** is a front view of upper and lower weaving plates supported by a weaving
13 plate supporter according to one embodiment of the present invention.

30
14 **FIG. 46** is a perspective view showing a combination of two templates on which a
15 bifurcated stent may be woven according to one embodiment of the present invention.

16 **DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS**

35
17 As shown in **FIG. 1A**, the present invention comprises a stent **10**, which may
18 include a common main body **20** and two legs **30** that comprise one coherent element.
19 The radially expandable and flexible tubular bodies of the stent may be created by using
20 the principle of plain weave. The arrangement of wires in a plain weave is illustrated in
40 21 **FIG. 1B**. As will be described below in greater detail, the weave is started on two
22 separate straight templates for making the legs **30** and is continued on a single straight
23 template for the common body **20**. The stent **10** may be made of nitinol wires and may
45 24 utilize nitinol's superelastic properties. In one embodiment, the nitinol may comprise
25 about 55-56% Nickel and about 45-44% Titanium (commercially available from Shape
26 Memory Applications in Santa Clara, CA). It is to be understood that stent **10** may also

1 be formed of any superelastic or pseudoelastic material. For example, shape memory
2 alloys such as FePt, FePd, FeNiCoTi with thermoelastic martensitic transformation, as
3 well as alloys such as FeNiC, FeMnSi, and FeMnSiCrNi, the shape memory effect of
4 which relies on stress-induced martensite, may be used.

5 As shown in FIG. 1, ends 15 of legs 30 have a plurality of closed structures.
6 These closed structures may be either small closed loops 45 or bends 50. Both bends 50
7 and small closed loops 45 may be formed by bending a wire 40 at a selected point located
8 between the bends of the wire. For most applications, the selected point of the bend or
9 small closed loop may be close to the mid-point of wire 40. The closed structures are
10 advantageous, because, for example, the closed structures formed by bending are less
11 likely to cause damage such as perforations or penetrations to the tubular structure stented
12 than are free wire ends.

13 Moreover, both loops 45 and bends 50 provide many significant advantages, some
14 of which are unexpected, over woven devices such as the stent disclosed in U.S. Patent
15 No. 4,655,771 to Wallsten (1987) (hereinafter, the stent therein will be referred to as the
16 "WALLSTENT"), which is hereby expressly incorporated herein by reference, which
17 have free wire ends. For instance, the Wallsten patent recognizes that the free wire ends
18 of the WALLSTENT should be protected, implicitly acknowledging the potential tissue-
19 damaging dangers such free, sharp wire ends pose. The Wallsten patent suggests
20 methods by which one can attempt to lessen these dangers, such as connecting the free
21 wire ends to each other by attaching U-shaped members to them through heat welding,
22 gluing or the like. These suggested methods are likely time-consuming and, as a result,
23 expensive. No such steps need to be taken in creating either loops 45 or bends 50 of the
24 present woven bifurcated stents as will be discussed below in greater detail.

25 Further, the connections resulting from the methods disclosed in the Wallsten
26 patent are likely more prone to mechanical failure than are loops 45 or bends 50 of the
27 present woven bifurcated stents. For example, welding can introduce anomalies such as
28 cracks (which may result from the non-uniform solidification, uneven boundaries, *etc.*);
29 voids or other irregularities resulting from porosity; inclusions (which include slag,

5
1 oxides, etc.); etc., into the welded metal that create stress concentrations and dramatically
2 increases the propensity for the welded connection to fail at those locations. In contrast,
3 the gentle curves and bends resulting in loops 45 and bends 50 are virtually free of any
10 4 such induced stresses and, as a result, are much less likely to fail.

5 The Wallsten patent also suggests gluing the free wire ends, a method that
6 provides even less structural integrity than can welding, because the resulting bond
15 7 between the joined wire ends is only as strong as the surface tension between the glue and
8 the metal used. Consequently, the joint created is more prone to failure than a welded
9 joint suffering from the anomalies just discussed.

20 10 Similarly, the Wallsten patent discloses first utilizing electric resistance heating to
11 weld together the points of crossing of the free wire ends in a ring around the stent and
12 then folding the free wire ends extending beyond the welded ring inwardly with light
25 13 plastic deformation through controlled heating. This method involves not only the likely
14 introduction of the anomalies discussed above that can result from welding, it also
15 involves an additional stress on the joints created as the free wire ends are folded
16 inwardly while being heated. Thus, this preferred joint is similar to the glued joint in that
30 17 it is likely even more prone to failure than one involving only welding.

18 In sum, the gentle curves and bends that may be used to create loops 45 and bends
19 50 of the present woven bifurcated stents provide devices with safer ends: no free wire
35 20 ends exist that may unintentionally penetrate and damage the wall of the structure into
21 which they are delivered; bends 45 or loops 50 are much less likely to mechanically fail
22 than are the free wire ends that are connected together using welding or glue; and the
40 23 likely time-consuming task of creating multiple welded or glued joints does not exist.
24 Further, while the closed structures 55 (discussed below in greater detail) may be
25 reinforced using methods similar to those suggested by the Wallsten patent (i.e., such as
26 by welding), the present woven bifurcated stents have fewer potential locations for using
45 27 such methods as either bends or loops exist at the ends of the legs of the present stents
28 (this is especially true considering fewer wires are generally needed for making the legs
29 of the present stents than are needed for making comparably-sized WALLSTENTS, even

equating one of the present wires to two wires as those are used in the WALLSTENT). As a result, the potential for mechanical failure of the present woven devices is reduced accordingly.

In addition to the foregoing benefits, loops 45 and bends 50 also provide advantages over the modified free wire ends disclosed in the Wallsten patent discussed above that are unexpected. For example, the inventors have found that the mesh of one of the legs of present woven bifurcated stents may be formed from fewer wires than can the mesh of a comparably-sized WALLSTENT (even equating one of the present wires to two wires as those are used in the WALLSTENT). Accordingly, the expansile force of one of the legs of present woven bifurcated stents of a given size may be maintained with fewer wires than would be needed to maintain the same expansile force of a WALLSTENT of the same size by simply increasing the mesh tightness (i.e., by increasing angle α in FIG. 1, discussed below in greater detail). Similarly, the inventors have found that the same result may be achieved by increasing the diameter of the present wires with or without adjusting the mesh tightness. As a result, the amount of metal needed for the legs of present woven bifurcated stents may be less than what is needed in another comparably-sized woven stent, such as the WALLSTENT. This reduction in necessary metal translates to a cost savings, and also means that patients are less likely to experience thrombosis and/or restenosis. As a further result, the variety of sizes that may be created for legs of the present woven bifurcated stents and the variety in the tightness of the weave of each is virtually unlimited, thereby facilitating virtually all potential applications.

Further, the inventors also discovered that virtually no shortening occurs while bending the present woven bifurcated stents, nor do the diameters of the legs or the common body of the present woven bifurcated stents increase during bending. Thus, it is easier to accurately and predictably position the present woven bifurcated stents in a tortuous anatomy than it is to position other woven stents that shorten more or suffer larger increases in diameter when bent, such as the WALLSTENT. For example, a tightly-woven leg of the present bifurcated stent, 2.5 cm long measured from the end of

1 the leg 1 the start of the common body (see FIG. 1A), 10 mm in diameter, formed from
2 10 0.006-inch wires may be maximally bent by bringing end 15 of the leg toward the
3 location at which it meets common body 20, and no shortening or diameter increase
4 occurs during maximal bending. In contrast, for a WALLSTENT formed from 24 0.005-
5 inch wires to behave similarly, the inventors found that it should be 6 cm long and 9 mm
6 in diameter; although, when manipulated in a similar manner, the WALLSTENT
7 experienced a 10% increase in diameter and some shortening. Thus, the length-to-
8 diameter ratios of the foregoing stents were 2.5 and 6.6, respectively.

9 At least 5 wires (the number of wires used being designated by n) may be used in
10 the plurality of wires that form each leg 30 of the stent 10. The number of wires that
11 form each leg 30 may vary. As shown in FIG. 1A, the wires 40 used to form the legs and
12 common body of stent 10 cross each other in a multiple locations at multiple angles. The
13 angles between the crossing wires are preferably obtuse, i.e. more than 90° (see angle a in
14 FIG. 1A). However, it will be understood that acute angles may be utilized. In an
15 exemplary embodiment, the angle may typically be about 150° for applications such as
16 the aorto iliac. In another exemplary embodiment, the angle may typically be about 160°
17 for applications such as the biliary tree (e.g., for tumorous lesions). In another exemplary
18 embodiment, the angle may be typically about 170° for applications such as the superior
19 vena cava (e.g., for space occupying lesions). Angle a should be increased as the desired
20 radial (i.e., expansile) force of the legs and common body of the bifurcated stent
21 increases. Further, the radial force of the legs and common body of the bifurcated stent
22 may generally be increased by increasing the diameter of the wires used. Thus, angle a
23 may be held constant while the diameters of the wires used are increased and, as a result,
24 the radial force of the legs and common body of the bifurcated stent increase. The weave
25 is contiguous, meaning that the weave of the common body is formed from the weaves of
26 the two legs, and from the level of the proximal end 25 of the common body 20 (the
27 bifurcation), $2n$ wires (assuming the same number of wires are used to form each leg) are
28 used to form the common body 20 of the stent 10. As shown, the distal portions 32 of the
29 legs 30 are positioned adjacent to the proximal end 25 (and hence the proximal portion)

5
1 of common body 20. At the distal or top end 28 (stent crown) of the common body 20,
2 adjacent wire ends 42 may be coupled together (as described below) to form closed
3 structures 55. Because common body 20 is formed from at least the wires making up legs
10 4 30, both ends of at least one wire from each of the legs is located proximate distal end 28
5 of common body 20. Wires 40 may range in diameter from about 0.005 inches to about
6 0.015 inches, depending on the application.

15 7 As used herein, the terms "distal" and "proximal" are relative terms only. The
8 inventors do not intend to impart any limitations of any kind through their use. For
9 example, as discussed above with respect to FIG. 1A, end 25 of common body 20 is
20 10 described as "proximal" while end 28 of common body 20 is described as "distal." In this
11 context, as in all other contexts herein, these terms only indicate relative proximity to
12 either the viewer of the figure, the operator of the delivery device on which the stent is
13 mounted, or the like. Accordingly, because end 25 is closer to the viewer of FIG. 1A
25 14 than is end 28, end 25 is described as being "proximal" and end 28 is described as being
15 "distal." Similarly, with respect to the discussion below pertaining to FIG. 5, the
16 orientation of stent 10 has been reversed in FIG. 5 from its orientation with respect to the
30 17 viewer depicted in FIG. 1A. Accordingly, as stated below with regard to FIG. 5, sheath
18 190 may be oriented over the "proximal" end of the stent—the same end that is described
19 as "distal" end 28 with respect to FIG. 1A.

35 20 Bifurcated stent 10 may also be formed from two wires. As illustrated in FIG.
21 1C, legs 30 have axes 31, and ends 15 (which may be termed proximal ends). Each leg is
22 shown as being formed from a single wire 40. First segments 46 of wires 40 are
23 separated from second segments 47 of wires 40 by bends in the wires (in the shape of
40 24 loops 45, but which may also be bends 50), which are located proximate ends 15 of legs
25 30. As shown in FIG. 1C, first segments 46 extend helically in a first direction around
26 axes 31 away from ends 15 of the legs. Similarly, second segments 47 extend helically in
45 27 a second direction around axes 31 away from ends 15 of the legs. First segments 46 cross
28 second segments 47 in a plurality of locations 48. As shown in FIG. 1C, locations 48
29 define loops 49, which touch each other such that the loops are contiguous. Loops 49 are

1 "contiguous" because, with the exception of the first and last loops, each loop shares a
2 point—location 48—with two other loops.

3 In further reference to FIG. 1C, ends 42 of second segments 47 are shown as
4 being located proximate the distal portions of legs 30 and proximate the proximal portion
5 of common body 20. These ends 42 may be left free (as shown) or may be may be
6 coupled together (as described below but not shown) to form closed structures. Ends 42
7 of first segments 46 are shown in FIG. 1C as forming common body 20. First segments
8 46 may be arranged about axis 21 of common body 20 in the same manner that the first
9 and second segments of the wires forming legs 30 may be arranged around axes 31. In
10 this regard, first segments 46 cross each other in a plurality of locations 48. As with legs
11 30, locations 48 define loops 49, which touch each other such that the loops are
12 contiguous. Ends 42 of first segments 46 may be coupled together to form closed
13 structure 55.

14 First and second segments 46 and 47 may be arranged in different ways with
15 respect to each other about axes 31. As shown in FIG. 1C, first segments 46 are
16 positioned farther from axes 31 than second segments 47 at alternate locations 48.
17 Although not shown, it will be understood to those of skill in the art, with the benefit of
18 this disclosure, that first segments 46 may be positioned farther from axes 31 at each
19 location 48. The same is true of first segments 46 with respect to axis 21.

20 In the embodiment of stent 10 depicted in FIG. 1C, loops 49 reside in a series of
21 planes that includes two groups of planes (not shown) for each leg 30 and for common
22 body 20, one of which includes the planes passing through the first, third, fifth, *etc.* loops
23 49, and the other of which includes the planes passing through the second, fourth, sixth,
24 *etc.* loops 49. The planes in each group are roughly parallel to each other. Additionally,
25 when body 10 is in its unconstrained state, the planes in one of the groups intersect the
26 planes in the other group (whether it is a leg or a common body in question) at acute
27 angles that fall within the range of slightly greater than 0° to about 45°. Moreover, axes

5
1 31 and 21 pass generally through the center of each of loops 49 for either the legs or the
2 common body of stent 10.

10
3 In an exemplary embodiment, legs 30 of stent 10 may be formed by various
4 methods of plain weave including hand weaving and machine weaving. The following
5 process is an exemplary embodiment of plain weaving according to the present invention.
6 As shown in FIG. 11, a template 300 having a diameter corresponding to the chosen
15 7 diameter of the leg of the stent is provided. The top of the template is equipped with
8 holes 302 around its circumference. Pins 304 are placed through the holes such that they
9 extend beyond the outer surface of the template on opposing sides. As shown in FIG. 11,
20 10 wires 40 are bent at about their midpoint around the pins. The bend may result in the
11 formation of bends 50 as shown, or the wires may be wrapped around the pins to form
12 small closed loops 45 (not shown). In one embodiment of leg 30, angle 17 of small
13 closed loop 45 or bend 50 (FIG. 1A) may be less than 90°. In a more typical embodiment
25 14 of leg 30, angle 17 may be equal to or greater than 90°, and may approach, but not
15 include, 180°.

30
16 Although only two pins are shown in FIG. 11, it is to be understood that this is
17 done for illustrative purposes only, and not to indicate the appropriate number of wires to
18 use in any given application. In an exemplary embodiment, template 300 is typically
19 formed of brass or copper, but may be formed of any suitable material capable of
35 20 withstanding the cure temperature discussed below, such as stainless steel. Similarly, in
21 an exemplary embodiment, pins 304 are typically formed of stainless steel, but may be
22 formed of any similarly suitable material. It is to be understood that the pins may be
23 supported by the template by any suitable means capable of withstanding the cure
40 24 temperature, including preforming, attachment by welding, threading, or the like.

45
25 As shown in FIG. 12, after the wires have been bent around the pins, the wires are
26 secured to the template to prevent them from returning to their original, straight, unbent
27 position. This may be necessary given the superelastic nature of wires such as nitinol and
28 the like (discussed below). As shown in FIG. 12, wires 40 are secured by securing wire

5
1 306 around the outside of wires 40 so as to secure wires 40 against the outside of the
2 template. In an exemplary embodiment, copper is typically used for securing wire 306,
3 but it is to be understood that any suitable wire capable of withstanding the curing
10 4 temperature of about 500°C discussed below may be used. After the wires are secured,
5 small weights 360 (shown in FIG. 15) are attached to the free ends of the wires using any
6 suitable means such as tying, or the like. In an exemplary embodiment, weights with
15 7 masses of approximately 50-100 grams may typically be used with wires having
8 diameters of between about 0.005 inches and about 0.011 inches. However, it is to be
9 understood that weights of different masses may be chosen so long as the wires are kept
10 under tension (*i.e.* straight) during plain weaving (as described below), and properly
20 11 balance the central weight (described below).

12 As shown in FIG. 13, a stand 330 with a circular plate 320 is provided with an
13 opening 325. The diameter of the opening may depend on the diameter of the template.
25 14 In an exemplary embodiment, an opening with a diameter of about 4.5 cm may be
15 typically utilized in conjunction with a template having a diameter of about 1.0 cm. It is
16 to be understood, however, that an opening with a diameter more closely corresponding
30 17 to the diameter of the template may be utilized. It is also to be understood that templates
18 300 may have slightly "D-shaped" ends 301 in order to facilitate placement within the
19 template 400 for the common body as shown in FIG. 23.

35 20 As shown in FIG. 14, before or after the weights are attached to the ends of
21 wires 40, the template is inverted. In an exemplary embodiment, the weights may be
22 typically attached to the free ends of the wires prior to inversion of the template such that
23 the wires are kept under tension and may be prevented from returning to their unbent,
40 24 nominal state. A central weight 340 may then be attached to the end of the template. In
25 an exemplary embodiment, the central weight may have a mass of approximately
26 600 grams, and may typically be hung from the pins. However, it is to be understood that
45 27 a central weight weights of a different mass may be chosen so long as the wires are kept
28 under tension (*i.e.* straight) during plain weaving (as described below), and properly
29 balance the smaller weights (described above). The central weight may be attached to the

5
1 template's end in any suitable manner, such as hanging from holes in the template itself,
2 *etc.*

10
3 Before or after central weight 340 is attached to the end of the template, the
4 inverted template is placed through opening 325, as shown in FIG. 15. In an exemplary
5 embodiment, the central weight may typically be attached to the inverted template after
6 the inverted template is placed through opening 325. As shown in FIG. 15, the wires 40
15
7 may be arranged fairly evenly around the circumference of the circular plate. As shown
8 in FIG. 16, in an exemplary embodiment of the present invention, 6 wires having 12 ends
9 numbered 1-12 (each wire having 2 ends) are shown as being arranged in a substantially
20
10 symmetrical fashion around circular plate 320. The weights 340 and 360 typically serve
11 to keep the wires under tension and in balance. Next, the plain weaving may take place.

25
12 In the manner shown in FIG. 17, the weave may be started by crossing one wire
13 end over the adjacent wire end. This crossing may be made in either a clockwise or
14 counterclockwise fashion. This crossing may be carried out as directed by the arrows
15 shown in FIG. 17. After a complete set of crosses (or one "turn") has been carried out,
16 the location of the crossed wire ends is as shown in FIG. 18. In an exemplary
30
17 embodiment, the resulting location of the wire ends may be achieved by crossing one wire
18 end over another in one direction while slightly shifting the wire end not crossed in the
19 opposite direction. In an exemplary embodiment, for example, this shifting may be about
35
20 15°. Thus, wire end 1 may be crossed in a clockwise direction over wire end 2, while
21 shifting wire end 2 about 15° counterclockwise. Once one turn has taken place, crossing
22 may begin in the same fashion, but in the opposite direction, as shown in FIG. 19. This
40
23 process may be repeated until the plain weave is complete.

45
24 The tightness of the wire mesh (*i.e.*, the angle α between the wires - FIG. 1A) may
25 be adjusted by changing the central weight. An increase in the central weight results in a
26 looser weave (decreased angle α between the wires) and vice versa.

50
27 The other leg of the stent is also woven in the same fashion.

5
1 In an exemplary embodiment of the plain weave process of legs 30 according to
2 the present invention, a conventional braiding machine may be utilized to arrange wires
3 40 in a plain weave to form legs 30 of stent 10. In another embodiment, a conventional
10 4 braiding machine may also be used to arrange wires in a plain weave to form the common
5 body of a trifurcated stent (described below). Such a braiding machine may be obtained,
6 for example, from Wardwell Braiding Machine Company in Central Falls, RI. The
7 manner in which a plain weave may be achieved using a conventional braiding machine is
15 8 displayed in FIG. 7 of U.S. Patent No. 5,419,231 to Earle, III *et al.* (1995), which is
9 hereby expressly incorporated by reference, as well as in FIG. 1 of U.S. Patent No.
10 5,485,774 to Osborne (1996), which is hereby expressly incorporated by reference.

20 11 Once the two legs have been woven, the templates 300 may be assembled with a
12 template 400 for the common body as shown in FIGS. 24 and 25A-C. The weaving is
13 then continued in the same manner around the common body template. The only
25 14 difference being that the number of wires being woven has doubled. Or, if the number of
15 wires in the pluralities of wires used to form the respective legs of the stent is different,
16 the number of wires in the plurality of wires that are woven to form the common body
30 17 includes the wires from both of the pluralities of wires used to form the legs. As
18 indicated in FIGS. 23-25C, in an exemplary embodiment according to the present
19 invention, template 400 may be generally cylindrical in shape. In such an embodiment,
20 the shape of a short portion of template 400 near end 401 into which the two leg
35 21 templates may be placed may be generally elliptical for a short portion. It is to be
22 understood, however, that a common body having a consistently cylindrical shape may
23 also be used.

40 24 After the weaving of the common body is complete, the adjacent wire ends 42
25 (FIG. 1A) may be coupled together to form closed structures 55 in any suitable fashion
26 capable of withstanding the heating described below, and capable of restraining the wires
45 27 from returning to their straight, unbent configuration as indicated in FIG. 26. In one
28 embodiment, the wire ends may be coupled together utilizing at least two twists as shown
29 in FIG. 26. In one embodiment, 6 twists may be used. Regardless of the number of

5
1 twists used, it is preferable to keep the twisted wire ends as short as possible. The shorter
2 the twisted wire ends are kept, the more resistant to bending the twisted wire ends are.
3 As a result, the twisted wire ends will be less likely to be inadvertently displaced during
10 4 insertion, positioning, repositioning, or retrieval, thus reducing their potential for causing
5 tissue damage. In other embodiments, the wire ends may be coupled together by bending
6 or crimping a metal clip around the wire ends, by tying the wire ends together with any
7 suitable material such as stainless steel wire, by welding, *etc.*

15
8 Other configurations of template 400 may also be utilized consistently with the
9 present disclosure. For example, template 400 may be provided with pins around which
20 10 the wire ends may be twisted in fashioning closed structures 55. Finish pins 800 may be
11 supplied on a ring, such as ring 802 depicted in FIG. 43, in any suitable fashion,
12 including, for example, through removable or permanent attachment. Ring 802 may be
13 configured to threadably engage template 400 as depicted in FIG. 43. In other
25 14 embodiments, ring 802 may be configured to engage template 400 by virtue of frictional
15 forces (not shown) or may be configured to be secured to template 400 as would a clamp
16 (not shown). Finish pins 800 may also be engaged with template 400 in the same manner
30 17 that pins 304 are engaged with template 300. As shown in FIG. 44, in such an
18 embodiment, template 400 may be provided with finish holes 804 similar to holes 302,
19 and finish pins 800 may be placed through finish holes 804. Ring 802 may also be
20 utilized in place of holes 302 and pins 304.

35
21 In an embodiment in which finish pins 800 are engaged with template 400 through
22 the utilization of ring 802, the number of finish pins utilized may be equal to the number
23 of wires that are used to form both legs. Template 400 may be threaded along any portion
40 24 of its length so as to best accommodate a variety of common body sizes. For example,
25 only a portion of template 400 may be threaded, as depicted in FIG. 43. Threads need
26 not be utilized with a ring that engages template 400 by virtue of frictional forces.

45
27 An advantage afforded by the use of ring 802 is the ease with which the precise
28 length of common body 20 may be achieved through the adjustment of the position of

5
1 ring 802. Further, the use of ring 802 also facilitates the symmetrical alignment of finish
2 pins 800 with the longitudinal lines formed by the points at which the wire segments
3 cross each other within the weave such that the symmetry of the weave may be
10 4 maintained and any structural benefits stemming from that symmetry may be realized.

5 In an embodiment in which finish pins 800 are placed through finish holes 804,
6 the number of finish pins utilized may be equal to one-half of the number of wires that are
15 7 used to form common body 20, since both ends of the finish pins will be utilized.
8 Template 400 may be provided with finish holes 804 along any portion of its length so as
9 to best accommodate a variety of stent sizes. For example, only a portion of template 400
10 may be provided with finish holes 804, as depicted in FIG. 44. As with ring 802, the use
11 of finish holes 804 advantageously allows the user to easily and precisely achieve a given
12 length for common body 20.

13 With the finish pins in place, once the wire ends of the wires have been woven
25 14 around the common body template, the wire ends may be secured around the finish pins
15 in any suitable manner to form closed structures, including by twisting, bending,
16 wrapping and the like. In one embodiment, the wire ends may be crossed, then bent
30 17 around a finish pin and then secured together with a short piece of thin-walled metal
18 tubing. Such a joint may then be reinforced by soldering, welding, or the like. A suitable
19 number of additional twists may be utilized after securing the wire ends around the finish
20 pins in forming closed structures. Securing wires (see securing wire 306 depicted in FIG.
35 21 12) may be utilized to secure the closed structures to the common body template during
22 annealing.

40 23 As a result of securing the wire ends around the finish pins, the angle created
24 between the crossed wire ends may be similar, if not identical to, the angle of the other
25 crossed wires in the woven legs described above. Advantageously, by using finish pins,
26 this angle between the crossed wire ends may be maintained, preventing the weave of the
45 27 woven stent from loosening. Were loosening to occur, the expansile or radial force of the
28 portion of the stent with the loosened weave could decrease, causing that portion of the
29 stent to remain elongated within the structure in which it is placed. Therefore, through

5
1 the use of finish pins and as a result of the correlating maintenance of the angle between
2 the crossed wire ends that are wrapped or twisted around the finish pins, the tightness of
3 the weave along the length of the legs and common body of the stent – from end to end –
10 4 may be consistent and resistant to loosening. Further, the expansile force of the end of
5 the stent having closed structures (*i.e.*, the distal end of the stent) may be comparable to
6 the expansile force of the other portions of the stent.

15 7 Another method of forming legs 30 of stent 10 and ultimately stent 10, according
8 to the present invention, is illustrated in FIGS. 31-42B. As shown in FIG. 31, the base
9 of template 300 may be equipped with longitudinal tabs 700 formed by two longitudinal
20 10 cuts connected by a transverse cut. The length of the cuts may be determined based upon
11 the size of the template chosen. For example, a template that is about 10 mm in diameter
12 may have longitudinal tabs with longitudinal cuts about 4 to 5 mm long, and the
13 connecting transverse cuts may be about 2 mm long. As illustrated in FIGS. 31, tabs 700
25 14 may be slightly elevated from the surface of template 300 and may be positioned
15 symmetrically around template 300.

30 16 FIGS. 31 and 32A and B also illustrate that wires 40 may be bent around tabs 700
17 at selected points located between the ends of the wires to form bent portions along wires
18 40. The bent portions may take the form of bends 50, as shown in FIG. 32A, or may be
19 further wrapped around tabs 700 to form loops 45, as shown in FIG. 32B. Angle *b* of
35 20 bends 50 or loops 45 may be less than 90°. In a more typical embodiment of the legs of
21 the present stents, angle *b* may be equal to or greater than 90°, and may approach but not
22 include, 180°. The bent portions may be arranged to define the ends of the legs. The
23 ends of the wires may then be weaved to create the legs using, for example, the following
40 24 machine weave method.

25 As shown in FIG. 33, the ends 42 of each wire 40 may be arranged around a pair
45 26 of bobbins 702. The length of the wire wound around each bobbin may be determined by
27 considering the total length of the wire needed to form the leg as well as the wire length

5
1 needed to arrange the bobbins around the weaving plates (shown in FIG. 34), which are
2 discussed below in greater detail.

10
3 As shown in FIG. 34, in one embodiment in which bobbins 702 are utilized, two
4 coaxially arranged weaving plates may be utilized. As shown in FIG. 35, upper weaving
5 plate 704 and lower weaving plate 706 may be positioned in different horizontal planes.
6 FIG. 35 illustrates that the weaving plates may be equipped with multiple bobbin
15 7 rods 708, the axes of which are substantially perpendicular to the weaving plates, on
8 which bobbins 702 may be slidably secured. (FIG. 35 depicts only 4 bobbins for the sake
9 of simplicity.) The weaving plates may be provided with holes therein through which
10 template 300 and/or wires 40 may pass, as shown in FIG. 35. Template 300 may be
11 secured to the base of the weaving machine chosen using any suitable means such as
12 template rod 710, around which template 300 may be slidably placed (FIG. 35).
13 Template rod 710 may be configured to firmly engage template 300 through frictional
25 14 forces (e.g., by tapering template rod 710). Instead of template rod 710, any appropriate
15 lock mechanism may be used to secure the base of the weaving machine to template 300.

30
16 As shown in FIGS. 36A and 37A, the pairs of bobbins 702 may be prepared for
17 weaving by arranging one bobbin on upper weaving plate 704 and the other bobbin from
18 the pair on lower weaving plate 706. Wires 40 may then be bent around tabs 700, and the
19 ends of the wires may be attached to bobbins 702 using any suitable means capable of
35 20 holding wires 40 under tension throughout the weaving process. An example of such a
21 mechanism is a one-way brake that allows bobbins 702 to rotate in a single direction only,
22 such that wires 40 may wind off bobbin 702. Simultaneously, such a brake may be
23 configured so as to continuously maintain tension in wires 40 by virtue of the brake's
40 24 resistance to the winding off of wires 40.

45
25 As shown in FIG. 36A, with the ends of the wires in place, the weaving may
26 begin by crossing the ends of the same wire, which results in the formation of a small
27 caliber loop 45 (FIG. 36B) at the site of the bent portion. In another manner of weaving

5
1 illustrated in FIG. 37A, the ends of different wires may be crossed first, resulting in bend
2 50 at the site of the bent portion (FIG. 37B).

10
3 As shown in FIGS. 38-39, the two weaving plates may be arranged such that the
4 surfaces thereof from which bobbin rods extend face each other. In this alternative
5 embodiment, the diameters of the plates may be the same or different. Wires 40 may be
6 arranged on bobbins 702 in the same manner as described above, as shown in FIG. 39.

15
7 Despite which of the aforementioned weaving plate arrangements is utilized, the
8 weaving plates rotate in opposite directions during the weaving process. The weaving
9 plates may be operated at any suitable speed. In this regard, a speed as low as 1 to 10
10 cycles per minute is acceptable. The weaving plates may also be driven by hand.

11 The weaving plates may supported and rotated using any suitable means. FIG. 45
12 illustrates one means of supporting and rotating weaving plates 704 and 706. (FIG. 45
25 depicts on 4 bobbins for the sake of simplicity.) As shown, weaving plate supporter 750
14 may be equipped with lower arm 752 and upper arm 754 for supporting lower and upper
15 weaving plates 706 and 704, respectively. Weaving plate drivers 760 may be secured to
30 16 the upper and lower arms of the weaving plate supporter and engaged with the weaving
17 plates in order to operate them. The drivers may be configured to operate in any suitable
18 fashion. For example, the drivers may be configured with a power source and provided
19 with gears of any suitable configuration for causing the weaving plates to rotate. The
35 20 drivers may also be configured to utilize magnetism or electromagnetism to rotate the
21 weaving plates. The drivers may be also be configured such that the weaving plates may
22 be rotated by hand. Further, although not shown, it will be understood to those of skill in
40 23 the art, with the benefit of this disclosure, that either or both of the upper and lower arms
24 may be provided with branches to which drivers may be attached. The drivers on the
25 branches could then be secured to or engaged with the top surfaces of the weaving plates
26 in the same fashion that drivers 760 are engaged with the bottom surfaces of the weaving
45 27 plates as shown in FIG. 45. Thus, in such an embodiment, both the top and bottom
28 surfaces of each weaving plate would be engaged with drivers.

5
1 Once the legs have been weaved, one of the weaving machines used to weave one
2 of the legs may be utilized to continue weaving the common body of the stent. To do so,
3 first, the bobbins and the corresponding wires may be rearranged around half of the
10 4 weaving plates of one of the "leg" machines. The template with the other woven leg may
5 be positioned and secured beside the first leg's template. The template configured for the
6 common body of the stent, if one is used, may then be placed over both leg templates, or
15 7 one template leg may be inserted into an opening of the common body template if such a
8 configuration is utilized. The bobbins and corresponding wires of the second leg may
9 then be arranged around the other half of the weaving plates, which is free of the first
10 10 leg's bobbins and wires. The weave may then be continued on the common body
20 11 template by rotating the weaving plates in opposite directions.

12 A bifurcated stent may also be created using only two templates consistent with
13 the present disclosure. As shown in FIG. 46, template 300 is shown having template
25 14 projections in the form of tabs 700 arranged around the template proximate the proximal
15 end thereof. The distal end of template 300 is shown as being hidden from view because
16 it is inserted into opening 425 of template 450. Template projections in the form of tabs
30 17 700 are also arranged around template 450 proximate the proximal end thereof. When
18 templates 300 and 450 are utilized together, a leg may be woven around template 300 in
19 any manner described above. Further, wires for the other leg may be bent around the tabs
20 arranged around the proximal end of template 450, and the ends of those wires may be
35 21 woven around portion 453, the portion of template 450 located proximally of opening
22 425. The wires from the two legs may be combined and woven around portion 457 to
23 create the common body and the stent. As shown in FIG. 46, portion 457 is the portion
40 24 of template 450 located distally of opening 425.

25 A braiding machine suitable for carrying the weaving process just described (*i.e.*,
26 utilizing the weaving plates) may be obtained, for example, from Wardwell Braiding
45 27 Machine Company in Central Falls, RI.

28 After the weaving process is complete, the ends of the wires may be twisted
29 together or coupled as described above to form closed structures. To make the process of

5 1 wire twisting faster and easier, the wires may be twisted with a special hand tool designed
2 for this purpose. Tool 712 illustrated in FIG. 41A follows the principle of an automatic
3 pencil. Jaws 714 of tool 712 are configured so that the ends of the wires may be firmly
10 4 held between jaws 714. Jaws 714 may be activated by push button 716 moving against
5 spring 718. After placing the wire ends into pre-formed gaps 720 located between jaws
6 714 (FIG. 41B), spring 718 expands (or returns to its unconstrained state) and retracts
7 jaws 714, securing the wire ends firmly between jaws 714 due to the pressure of outer
15 8 housing 722 acting to close jaws 714. Outer housing 722 may then be rotated to create
9 multiple twists of the wire ends. As illustrated in FIGS. 42A and 42B, the twisted ends
10 of common body 20 may be secured to template 400 using transverse tabs 724, which
20 11 may be formed the same way as longitudinal tabs 700.

12 Next, the bifurcated stent may be heated at about 500°C for 5 to 15 min,
13 preferably about 12 to 15 min and then allowed to cool to room temperature. In one
25 14 embodiment, the bifurcated stent may be heated to 500°C for 15 minutes. As a result, the
15 wires of the stent may exhibit superelastic properties. The initial shape of a stent
16 programmed with superelasticity may be deformed by applying a force thereto. The
30 17 shape memory of the stent may then be activated by removing the force, and the stent may
18 substantially recover its initial shape. As used herein, "substantially recover" means that
19 recovery need not be such that the exact original shape be regained. Rather, it is meant
20 that some degree of plastic deformation may occur. In other words, recovery need not be
35 21 total. In another embodiment, the stent may be programmed with thermal shape memory
22 by heating it to about 500°C for about 60 to 120 minutes, typically about 120 minutes, in
23 an oven. In one embodiment, the bifurcated stent may be heated to 500°C for 120
40 24 minutes. The initial shape of a stent programmed with thermal shape memory may be
25 deformed upon application of a force at a first temperature. The force may be removed,
26 and the stent may remain deformed. The shape memory of the stent may then be
27 activated by heating the stent to a second temperature, at which temperature the stent may
45 28 substantially recover its initial shape.

5
1 To make the final shape of the stent including the creation of slightly tapered legs
2 and the adjustment of the angle between the common body and the legs, the stent may be
3 remodeled on another template and reheated. The attachment to the remodeling template
10 4 may be achieved in a fashion similar to the manner in which the wires are originally
5 attached to the template, *e.g.*, wrapped copper wires. Reheating may be done using a
6 similar time and temperature as the initial heating. The stent crown 28 may also be flared
7 for better fixation of the stent 10, with remodeling and reheating. After cooling down to
15 8 room temperature, the stent wires may exhibit superelastic properties. It is to be
9 understood that if the stent is remodeled a number of times and it is not intended that the
10 stent be programmed with thermal shape memory, care should be taken not to exceed a
20 11 total heating time (which includes the first heating time *and* the second heating time, *etc.*)
12 of about 60 minutes, because at about 60 minutes, the stent may be programmed with
13 thermal shape memory.

25 14 In an exemplary embodiment of stent 10, after heating and cooling, it is preferable
15 to further reinforce the coupled wire ends 42 of closed structures 55 (particularly if they
16 were coupled using twists) by any suitable means such as point welding, soldering,
30 17 pressure welding, or the like, in order to better ensure that the coupled wire ends will not
18 separate during delivery (to be discussed in detail below). Coupled wire ends 42 may be
19 soldered by removing any oxide layer that may have formed over the relevant portions of
20 the wires used, and applying solder to those portions. Soldering may be enhanced by first
35 21 wrapping coupled wire ends 42 with thin stainless steel wires. In an exemplary
22 embodiment, point welding is preferred to soldering, because point welding is easier to
23 perform than soldering, and may be more suitable with regard to long-term implantation
40 24 of the stent.

25 *Biodegradable Version*

26 The bifurcated stent of the present invention (and the trifurcated stent discussed
45 27 below) may be formed with filaments made of biodegradable material so as to form a
28 self-expanding, bioabsorbable, biodegradable stent that may, in addition to functioning as
29 a stent, function as drug or nutrient delivery systems as a result of the material used.

5
1 Many factors may be considered in choosing materials from which to form the
2 biodegradable bifurcated stent of the present invention. In one embodiment, the
3 biodegradable stent of the present invention may be formed from materials of minimal
10 4 thickness so as to minimize blood flow blockage and facilitate bioabsorption. In another
5 embodiment, the material may be chosen so as to exhibit sufficient radial strength to
6 allow the body formed to function as a stent. The material from which the biodegradable
7 stent may be formed may also degrade within the bloodstream over a period of weeks or
15 8 months, so as not to form emboli. However, the material may be chosen such that the
9 stent does not degrade before an endothelial layer forms in the stented vessel or structure
10 in cases in which vascular stenoses of arteriosclerotic origin are treated. The material
20 11 chosen may be chosen to be compatible with surrounding tissue in the vessel as well as
12 with blood.

13 The bifurcated biodegradable stent may be formed by plain weave using the
25 14 methods above described. The size of the filaments used may vary according to the
15 application. In some embodiments, the filaments may be reduced in size in comparison
16 to the size of wires used in comparable applications involving non-biodegradable stents.
30 17 In other embodiments, the number of filaments used may be increased in comparison to
18 the number of wires used in comparable applications involving non-biodegradable stents.

19 The minimum number of filaments that may be used to create the legs of the
20 bifurcated stent may be about 5. In one embodiment, 12 filaments may be used. The
35 21 minimum number of filaments that may be used to create the legs of the trifurcated stent
22 (described below) may be about 5. In one embodiment, 8 filaments may be used. The
23 minimum number of filaments that may be used to create the common body of the
40 24 trifurcated stent (described below), prior to the legs being added thereto, may be about 10.
25 In one embodiment, 8 filaments may be used. In creating the stent using plain weave, the
26 angle of the crossed filaments (described above as angle α) may vary as described above,
45 27 but is typically 150-160°. In one embodiment, the angle of the crossed filaments may be
28 as large as possible to achieve the largest radial force possible and further ensure that the
29 stent may have enough expansile force to remain in place after being delivered. The

5
1 filament ends, after plain weaving is complete, may be coupled together to form closed
2 structures using any suitable means such as by heat treatment or sealing, gluing, tying,
3 twisting, crimping, taping, or the like.

10
4 In one embodiment, the filaments used may be made of polyglycolic acid
5 ("PGA"), poly-L-lactic acid ("L-PLA"), polyorthoesters, polyanhydrides,
6 polyiminocarbonates, or inorganic phosphates. These polymers are commercially
15 7 available from United States Surgical Corporation, Norwalk, CT; Birmingham Polymers,
8 Inc., Birmingham, AL; and Ethicon, Sommerville, NJ, for example. One factor to
9 consider in choosing a material from which to make the filament will be the goal of the
20 10 stent placement. For example, in an embodiment in which the stent serves mainly as a
11 drug delivery system, PLA may be used because of its rapid degradation time. In another
12 embodiment in which the stent serves mainly to maintain the patency of the vessel (*i.e.*,
13 keeping the vessel open) and as a scaffold or frame for the development of a new
25 14 endothelial layer, PGA may be used considering its high strength and stiffness. In other
15 embodiments, glycolide may be copolymerized with other monomers to reduce the
16 stiffness of the resulting fibers that may be used.

30 17 In another embodiment, any of these filaments may be provided with about 0.05
18 to 0.25 percent by weight of a basic metal compound, such as calcium oxide, calcium
19 hydroxide, calcium carbonate, calcium phosphate, magnesium oxide, magnesium
35 20 hydroxide, magnesium carbonate, magnesium phosphate, sodium phosphate, potassium
21 sulfate or the like, to increase the *in vivo* strength retention of the biodegradable stent by
22 about ten to twenty percent or more, as described in U.S. Patent No. 5,478,355 to Muth *et*
23 *al.* (1995), which is hereby expressly incorporated by reference. As used herein, "*in vivo*
40 24 strength retention" refers to the ability of a biodegradable body to retain its strength (*i.e.*,
25 the breaking load of the body) after being implanted or delivered into a living creature. In
26 yet another embodiment, a filament obtained from a polymer containing about 15 to about
45 27 30 mole percent glycolide in a melt spinning operation, as described in U.S. Patent No.
28 5,425,984 to Kennedy *et al.* (1995), which is hereby expressly incorporated by reference,
29 may be used to form a biodegradable body.

5
1 The filaments of the biodegradable stent may incorporate one or more drugs that
2 positively affect healing at the location where the stent is delivered. In one embodiment,
3 these drugs may include anticancer drugs such as paclitaxel (which is commercially
10 4 available as TAXOL, from Bristol-Myers Squibb in Princeton, NJ) or docetaxel (which is
5 commercially available as TAXOTERE, from Rhone-Poulenc Rorer in Collegeville, PA),
6 fibroblast/smooth muscle cell proliferation-preventing agents, and antithrombogenic
15 7 drugs such as heparin which is commercially available from Wyeth-Ayers in
8 Philadelphia, PA.

9 One or more drugs may be incorporated into a polymer using any suitable means.
20 10 For example, in one embodiment, the drugs as a solute may be dissolved in the
11 biodegradable polymer as a solvent to form a solution. The solution may then be
12 hardened into a fiber from which the stent may be woven. In another embodiment,
13 simple mixing or solubilizing with polymer solutions may be utilized. The drugs may
25 14 also be dispersed into the biodegradable polymer during an extrusion or melt spinning
15 process. In yet another embodiment, the biodegradable fibers that have already been
16 formed may be coated with drugs.

30 17 The biodegradable filaments may be rendered radiopaque to facilitate their
18 monitoring under fluoroscopy and/or their follow-up using radiographs, fluoroscopy, or
19 computerized tomography. The methods described above for incorporating the drugs into
35 20 the polymer may be used to mix radiopaque salts, such as tantalum, with the polymer.

21 As used herein, "degradation time" refers to the time during which the
22 biodegradable stent maintains its mechanical integrity. One factor that should be
40 23 considered in choosing a polymer in light of its degradation time is that the polymer will
24 lose its mechanical integrity before it is completely absorbed into the body. For
25 example, pure polyglycolide (PGA) sutures lose about 50% of their strength after 2
26 weeks, and 100% at 4 weeks, and are completely absorbed in 4-6 months. For vascular
45 27 applications (*i.e.*, applications in which the stent is placed within a vessel in a body),
28 polymers having degradation times of about one to twenty-four months may be used,
29 depending on the application. In a typical embodiment, a polymer having a degradation

1 time of about one to three months may be used. In choosing a polymer for non-vascular
2 applications such as the esophagus, colon, biliary tree, ureter, *etc.*, one should consider
3 the polymer's ability to withstand the chemical stimuli in the given environment.

4 During the degradation time of the biodegradable stent, a new endothelial layer
5 may form on the surface of the stent. The rate of the release of the drugs which may be
6 incorporated into the polymers may be controlled by the rate of degradation of the
7 biodegradable material used. Thus, the rate of release of a drug may act as a control
8 quantity for the rate of degradation. At the same time, other agents such as fibronectin
9 from human plasma (commercially available from Sigma, St. Louis, MO) may be added
10 to the polymer used (using any suitable means described above for incorporating drugs
11 into the chosen polymer) and may affect the rate of biodegradation. For example,
12 fibronectin may accelerate the growth of cells around the surrounding stent, which, in
13 turn may accelerate the resorption reactions around the stent.

14 In one embodiment of a biodegradable stent according to the present invention,
15 one or more shape memory wires may be added to the either the legs or the common body
16 of the bifurcated or trifurcated stents for reinforcement after forming the leg or common
17 body using plain weave. Such wires may comprise nitinol or any other comparable
18 material above described. In one embodiment, the wires may be formed from nitinol
19 having about 55 to 56% Nickel and 45 to 44% Titanium (Shape Memory Applications).
20 The wire or wires may be incorporated into the woven biodegradable structure by
21 threading the wire in and out of openings in the leg several times. In one embodiment,
22 the manner in which the wire is threaded in and out of openings in a leg is shown in
23 FIG. 28. In FIG. 28, designation 520 shows reinforcement wire 510 passing outside
24 biodegradable leg 500, and designation 530 shows reinforcement wire 510 passing inside
25 biodegradable leg 500, thus showing how wire 510 may be threaded in and out of
26 openings in leg 500. As shown in FIG. 28, the reinforcement wire(s) 510 may be led
27 between (*i.e.*, parallel to) two biodegradable filaments 540 and may follow their helical
28 course. As shown in FIG. 28, reinforcement wire 510 may be secured to leg 500 with
29 loops 550, or any other suitable means such as tying, twisting, or the like. Loops 550 may

5
1 be placed around a filament or around the intersection of one or more filaments. As a
2 result, the wire can move in harmony with the weave and will not interfere with the
3 movement of the filaments in the weave. By activating the shape memory of
10 4 reinforcement wire 510, ends 560 and 570 of leg 500 may be pulled together, resulting in
5 a tighter weave. As a result, the expansile force of the stent and its resistance to outer
6 compression may significantly increase. In one embodiment, loops 550 may also be used
15 7 in securing leg 500 to a delivery system.

8 In another embodiment shown in FIG. 29, in which a reinforcement wire is
9 threaded in and out of openings in a biodegradable leg according to the present invention,
20 10 reinforcement wire 510 may be bent at a selected point located between its ends, typically
11 at about the mid-point of the wire, and a small loop 512 may be created (similar to the
12 small closed loops described above). As shown in FIG. 29, small loop 512 may be
13 entwined around a filament or the intersection of one or more filaments, and
25 14 reinforcement wire 510 may be threaded in and out of the openings in leg 500 as
15 described above, and may be secured to leg 500 with loops 550, or any other suitable
16 mean, as above described. Both portions 514 of reinforcement wire 510 may be
30 17 symmetrically led along both sides of leg 500 following the sinuous/helical course of the
18 biodegradable filaments. As described earlier, by activating the shape memory of
19 reinforcement wire 510, ends 560 and 570 of leg 500 may be pulled together, resulting in
20 a tighter weave. As a result, the expansile force of the stent and its resistance to outer
35 21 compression may significantly increase. In one embodiment, loops 550 may also be used
22 in securing leg 500 to a delivery system.

23 In one embodiment, the size of reinforcement wire 510 may range from about
40 24 0.005 inches to about 0.012 inches. It is to be understood that increasing the size of
25 reinforcement wire 510 may increase the force with which ends 560 and 570 are pulled
26 together when the shape memory of the wire is activated. It is to be understood that using
45 27 more than one wire may have the same effect as increasing the size of the wire.

1 In one embodiment, reinforcement wire(s) 510 may be formed around a template
2 as above described. The reinforcement wire(s) may then be programmed with
3 superelasticity or thermal shape memory as described herein.

4 *Bench-work*

5 With regard to the biodegradable version of the stents according to the present
6 invention, the inventors have used an open-ended plain woven nylon leg (that is, the
7 filament ends were not coupled together to form closed structures after weaving) for
8 initial bench work. The leg was woven using 0.007 inch nylon filaments. The number of
9 filaments used was 16, and the unconstrained diameter of the leg was 11 mm. In an
10 unconstrained state, the size of the weave holes was approximately 1 mm. The expansile
11 force of the leg was relatively good, and after maximum elongation the leg readily
12 reverted to its unconstrained diameter. Compressing the leg from its two ends
13 longitudinally, the expansile force could be increased considerably. At the maximal
14 longitudinal compression, the diameter of the leg was 13 mm. Holding both ends of the
15 leg, it became virtually incompressible.

16 A 0.006" nitinol wire was threaded through the holes of the unconstrained mesh in
17 the manner described earlier. The wire was a straight nitinol wire and was not formed on
18 a template and programmed with either thermal shape memory or superelasticity. The
19 straight wire caused the leg to elongate and the unconstrained diameter of the leg
20 decreased to 9.5 mm (13% lumen-loss though the other characteristics of the leg did not
21 change. The woven tubular leg could be elongated completely as well as compressed
22 maximally.

23 **Possible Applications of the Stent**

24 The present invention makes it possible to use stent 10 in several vascular and
25 non-vascular territories where bifurcated anatomical structures are present. The range of
26 possible vascular applications includes the aorto-iliac bifurcation, the superior vena cava
27 (SVC) junction, and the inferior vena cava (IVC) junction. After recanalizing an
28 extended aorto-bi-iliac obstruction (Leriche syndrome), the stent would be ideal to

5
1 maintain the lumen of the aorto-iliac bifurcation. For treatment of an abdominal aortic
2 aneurysm, the stent may be covered using some kind of elastic covering material, turning
3 it into a stent-graft. The stent would also be an ideal solution for treatment of tracheo-
10 4 bronchial obstructions. The bifurcated stent may also be used in hilar biliary stenoses
5 (e.g., Klatskin tumors). For stenting malignant stenoses, the stent may be equipped with a
6 special cover (e.g., of polyurethane or silicon) and/or with an anticancer coating. Another
15 7 possible application may be stenting the venous side of a hemodialysis access graft after
8 dilating the venous stenosis to maintain the lumens of both the graft and the parent vein.

9 The stent according to the present invention makes it possible to change the
20 10 angles between the crossing wires (e.g., creating a tighter weave and/or a tapering shape),
11 resulting in a controlled expansile force. Selecting the angles between the crossing wires
12 so that they are close to the practical maximum of 180°, the expansile force of the stent
13 may be increased to the point that a virtually incompressible stent may be created. As
25 14 discussed in the Examples herein, the *in vitro* studies suggest that the same size nitinol
15 stent with a similar mesh tightness as the WALLSTENT (Schneider, Minneapolis, MN;
16 Boston Scientific Vascular) may exert much more resistance to outer compression (see
30 17 Tables 2 and 3 below). This feature may be utilized in some vessel stenoses/obstructions
18 caused by space occupying malignancies (e.g., SVC syndrome), where high outer
19 compressive forces are present.

35 20 The angle between the main body 20 and the legs 30 may be adjusted to
21 accommodate the patient's anatomy. Because of the flexibility of the stent, the angle
22 between the legs 30, which may be selected according to the average sizes of the given
23 anatomical structure, may be used in the majority of the cases. The angle for a
40 24 tracheobronchial application may be about 45 to 70°. In humans, the trachea bifurcation
25 typically has an angle of about 65°. Similarly, the cross-section of the main body 20 may
26 also be changed from a round to somewhat elliptical shape, if necessary (e.g., tracheo-
45 27 bronchial application). For better fixation of the stent, the crown 28 of the common body
28 20 may be flared. The length of the stent's common body 20, as well as the legs 30 may
29 also be varied according to the particular requirements of the anatomy.

5
1 The stent may then be stretched to reduce its diameter as much as possible. Then,
2 using a delivery system according to the present invention, which may hold the stent in a
3 stretched state, the stent may be inserted into the bifurcated tubular structure to be
10 4 stented.

5 Delivery Systems and Stent Deployment

15 6 The present invention also includes delivery systems for the stent, which may vary
7 according to the applications of the stent. Two basic versions of the delivery systems are
8 the tracheo-bronchial type and the aorto-iliac type.

20 A. Tracheo-Bronchial Application

10 a. First Embodiment

25 11 FIG. 3 is a diagram of an exemplary embodiment of the front part of a delivery
12 system 100 according to the present invention, which comprises two small caliber tubes
13 or legs 110 (which may be constructed of Teflon, PVC, Nylon, or any other suitable
14 material) which fit within either a funnel-shaped sheath (or a Y-shaped) piece 120 (which
30 15 may be constructed of a similar material to 110). A single lumen tube 140 also fits within
16 this funnel or the common trunk of the Y-shape piece 120. Tube 140 may be made of a
17 thin-walled, flexible, metal microtubing. In one embodiment, tube 140 may be made of
35 18 nitinol (commercially available from Shape Memory Applications). The distal end 115 of
19 each small caliber tube may be equipped with two holes positioned close to the tip. Two
20 securing wires 130, which in an exemplary embodiment may be nitinol wires between
21 about 0.009"-0.013" (as used herein, 0.009" means 0.009 inches, and the like) thick, one
40 22 in each leg 110, may be used to hold the distal end of the stent legs 30. Other materials
23 from which securing wires 130 may be formed include any superelastic or pseudoelastic
24 materials. In one embodiment, securing wires 130 (and all other wires described in A.
45 25 and B. herein) may be nitinol wires which comprise about 55-56% Nickel and about 45-
26 44% Titanium (commercially available from Shape Memory Applications). In an
27 embodiment in which the securing wires of the present invention are nitinol (including

5
1 wires 130 and the others discussed below), the nitinol securing wires may be heat treated
2 as described herein or purchased from a manufacturer such that the superelastic properties
3 of the nitinol may be utilized. These nitinol securing wires 130 come out from the lumen
10 4 140 through the proximal hole and go back through the distal hole, forming a small
5 profile tight loop 135 between the two holes, as shown in FIG. 3. The nitinol securing
6 wires 130 are threaded into the single lumen tube 140 after passing the funnel or the
7 Y-shape piece 120. The distal 1.5-2.0-cm-long ends of the nitinol securing wires 130
15 8 may be equipped with a small piece of soft tip to facilitate maneuvers within the tracheo-
9 bronchial system. The bifurcated stent 10 is placed over this Y-shaped tubing assembly
10 with the distal legs attached to the tight nitinol wire loops between the holes. That is,
20 11 wire 130 may be threaded through the proximal hole, through a closed structure (such as a
12 bend or small closed loop or another opening in the weave), and back into the lumen of
13 tube 110 through the distal hole.

25 14 It is to be understood that in an exemplary embodiment of delivery system 100
15 according to the present invention, multiple securing wires may be utilized instead of one
16 in each leg 110 of the delivery system. In this embodiment, the distal ends of legs 110
30 17 should be equipped with a series of pairs of holes arranged substantially evenly around
18 the circumference of the legs.

35 19 It is to be understood that in an exemplary embodiment of delivery system 100,
20 two steerable guidewires with good torque control, preferably made of nitinol
21 (commercially available from Microvena Co. in White Bear Lake, MN), may be utilized
22 instead of flexible pieces of soft tip. The guidewires may be equipped with a soft
23 radiopaque tip (made from platinum, tungsten, or any other suitable material) and may be
40 24 placed in the lumens of the tubes 110 and in the single lumen tube 140. In a further
25 embodiment, these tubes may be equipped with two channels; one channel may be
26 created for the securing wires and the other for the guide wires. As a result, the
45 27 movement of the guidewires during manipulations will not interfere with the firm
28 position of the securing wires and vice versa.

5
1 To create some free covered space around tube 140 immediately behind the
2 conflation of tubes 110, a short segment 160 of a larger caliber thin-walled sheath may
3 cover tube 140 as well as the proximal ends of the small caliber tubes 110. If the
10 4 connection between the small caliber tubes and tube 140 is created by a funnel shaped
5 piece 120, 120 and 160 may be fabricated from the same piece (as shown in FIG. 3). If a
6 Y-shape piece is used, segment 160 may be attached to the common trunk of the Y-shape
15 7 piece 120. In such an embodiment, 120 and 160 may be fabricated from the same piece.
8 The created space may be used to hide inverse tabs attached to the proximal part of the
9 delivery system 100.

20 10 Coaxially, a larger tube 170 (which may be Teflon or any other material described
11 above and two French-sizes larger than tube 140) may be positioned over tube 140. Near
12 its distal end 175, tube 170 may be equipped with some metal hooks 180 facing
25 13 proximally (FIG. 3). These inverse metal hooks 180 may be used for securing the
14 proximal end of the common body 20 of stent 10.

15 After securing both the legs 30 and the common body 20 of stent 10 using the low
30 16 profile nitinol loops and the inverse hooks 180 (which may be threaded through the
17 closed structures or other openings near the stent's end), the stent may be maximally
18 stretched over the tubes, as shown in FIG. 5. An outer thin-walled sheath 190 may be
19 pulled over the proximal end of the stent. As a result, the proximal end of the stent 10
35 20 may be fixed to the delivery system 100, and simultaneously the hooks will be covered.
21 Separate lock mechanisms attached to the proximal ends of the parts of the delivery
22 system 100 will ensure that the stent 10 remains in the extended state during delivery.
40 23 Separate lock mechanisms may also be used to secure the nitinol wires 130 and prevent
24 the premature release of the stent 10.

25 As shown in FIG. 2, a push-button lock/release switch mechanism 90 (such as a
45 26 FloSwitch®HP device from Meditech/Boston Scientific Corp., Watertown, MA or a
27 CRICKETT device from Microvena in White Bear Lake, MN) may be used to secure tube
28 140 to tube 170 when necessary. When switch 91 of push-button lock/release switch

5 1 mechanism 90 is in an open or unlocked position, the two tubings are unlocked and as a
2 2 result tube 170 moves freely on tube 140. This free movement allows for the stent to take
3 3 on its unconstrained shape and size. When switch 91 of push-button lock/release switch
10 4 mechanism 90 is in a closed or locked position, the two tubings are locked, the two tubes
5 5 cannot move relative to each other, and the stent may be maintained in a completely
6 6 stretched state. Tube 170 may be provided with a hub or flange for facilitating the
15 7 attachment of push-button lock/release switch mechanism 90 thereto.

8 8 As shown in FIG. 2, an end fitting 92 with a side-arm 93 may be attached to tube
9 9 140 using a Luer lock mechanism. The attachment between tube 140 and end fitting 92
20 10 may be facilitated by providing tube 140 with a hub or flange (not shown). End fitting 92
11 11 may be equipped with two tightening screw mechanisms 94, one for the two steerable
12 12 guidewires 95 (only one of which is shown), and the other for the securing nitinol wires
13 13 130 (although one securing wire is illustrated, it is to be understood that more than one
25 14 may be used in this exemplary embodiment). These tightening screws may be used to
15 15 secure the guidewires and the nitinol securing wires in position during the stent delivery.
16 16 The proximal ends of the securing nitinol wires 130 may be held together with a "handle"
30 17 piece 97, facilitating their simultaneous movement during stent deployment. End fitting
18 18 92 may be equipped with separated lumens in a double channel system. The guidewire(s)
19 19 may be placed in one lumen, and the securing wire(s) may be placed in another lumen.

35 20 With regard to the securing wires described herein, which may be used to secure
21 21 the present stents to the delivery systems described herein, it will be understood to those
22 22 of skill in the art, having the benefit of this disclosure, that the securing wires may be
23 23 controlled by creating openings in whatever tube the securing wires are positioned within
40 24 (the holes generally being made near the proximal end of the relevant tube) and threading
25 25 the proximal ends of the securing wires through those holes. In this way, the relevant
26 26 portion of the stent being delivered may be released by pulling the proximal ends of
45 27 securing wires, which are positioned exterior of the relevant tube.

5
1 At the first stage of deployment, the delivery system 100 may be inserted through
2 a tracheal tube. Both legs 110 of the delivery system 100 may be advanced in the main
3 bronchi so that the junction of the legs 110 can be caught by the carina of the trachea.
10 4 Holding the delivery system 100 in this position, the proximal portion of the common
5 body 20 may be released. To do so, the outer thin-walled sheath 190 may be withdrawn
6 to expose hooks 180. Tube 170 with hooks 180 may be moved distally to unhook the
15 7 stent. Tube 170 with hooks 180 may then be moved further distally so that hooks 180
8 will be covered by segment 160 attached to the Y-piece. The wires 130 of each leg may
9 be pulled back one after the other, and legs 30 of the stent will be released.

20 10 The stent may be released by starting the deployment with the release of the legs.
11 The method of deployment which releases the common body of the stent first may be
12 preferred to a first-legs-release, because the released common body can secure itself
13 above the carina, and thereby significantly decrease the chance of deploying the stent
25 14 higher than optimal within the trachea. No matter which order of release is used, after
15 hiding the proximal hook mechanism in the thin-walled sheath piece 160, the delivery
16 system can be easily withdrawn and removed.

30 17 **b. Second Embodiment**

18 In an alternate embodiment shown in FIG. 4, the proximal portion of the delivery
19 system does not use the inverse hook mechanism. Instead, the proximal end of the stent
35 20 may be secured to tube 170 with a tight nitinol loop as above described, similar to that
21 used for securing the distal ends of the stent legs to tubes 110. To achieve an even
22 arrangement of the stent's twisted wires around the tube, multiple tapered nitinol wires
40 23 130 (having tapered segment a) may be threaded through multiple pairs of holes arranged
24 substantially evenly around the circumference of the tube, as shown in FIG. 4. In this and
25 all exemplary embodiments utilizing securing wires, the ends of the securing wires may
26 be tapered, making it possible to avoid a crowded arrangement of the coupled wire ends
45 27 on tube 170.

1 In general, the strength of the small profile nitinol loops depends primarily on the
2 size of the wire used. But the size and shape of the holes, as well as the relationship of
3 the corresponding holes (that is, whether they are arranged parallel to the longitudinal
4 axis of the tubing or run obliquely) may have an impact on the strength of the securing
5 loops.

6 The tracheo-bronchial type versions of the delivery system described above may
7 also be used for an SVC bifurcated stent placement from a femoral vein approach, or for
8 an IVC bifurcated stent placement from a jugular approach.

9 B. Aorto-Iliac Application

10 As shown in FIG. 6, the delivery system 200 of this alternate embodiment may
11 comprise two straight tubes 210 and 220 (which may be Teflon or any other material
12 described above, and may be preferably D-shaped, although round shapes may be used) of
13 different lengths. The shorter tube 210 is flexibly connected to the longer tube 220 (in
14 some applications, the connection may be at about the mid-point of tube 220), thereby
15 creating a joint. At the point of connection, a notch may be cut on the longer tube 220
16 facing toward the shorter tube 210. Notch 215 may facilitate movement of the shorter
17 tube 210 at the joint, and with the two tubes in a side-to-side arrangement forming a
18 slightly elliptical cross-section, the size of the delivery system may be minimized.

19 The flexible connection between the two tubes may use, in an exemplary
20 embodiment, a wire 230, as shown in FIG. 5, such as a 0.011"-0.015" wire made of
21 nitinol (commercially available from Shape Memory Applications) or any pseudoelectric
22 or superelastic material. The wire 230 may be fed through two holes positioned on the
23 shorter tube 210 close to its proximal tip. The wire 230 may form a low profile, tight
24 loop 235 (like the loops described above) between the holes and may be used to secure
25 the proximal end of the contralateral or left leg 30 of the Y-shape stent in the manner
26 described above. The wire 230 may then be placed within the lumen of the shorter
27 tubing. At the site of the attachment, the wire 230 may be contiguously led through a
28 hole in the longer tube 220 to the lumen of the longer tube 220. The wire 230 may be led

5 1 almost to the distal end of this tubing. Another low profile, tight loop 235 may be formed
2 from the wire 230 at any suitable location along the longer tube 220, in order to
3 strengthen the connection between the two tubes. In this regard, low profile loop 235 is
10 4 shown about mid-way between notch 215 and distal end 222, but it will be understood
5 that the loop may also be located close to distal end 222.

6 A small-profile, tight securing loop 225 (like those described above) may be
15 7 created using wire 240 (which may be made of nitinol (Shape Memory Applications) or
8 other suitable materials described above) close to the distal end 222 of the longer tube
9 220. This loop may be used to secure the common body 20 (stent crown) of the Y-shape
10 10 stent 10 to tube 220 in the manner above described. Within the same lumen, another wire
20 11 270 (which may be made of nitinol (Shape Memory Applications) or other suitable
12 materials described above) may be placed, which may form another small-profile, tight
13 loop 275 near the proximal end of the longer tube 220. This loop may be used for
25 14 securing the ipsilateral or right leg of the stent.

15 To facilitate the positioning of the contralateral leg 30, a monofilament 250 which
16 may be a 3.0-4.0 (metric 1.5-2.0) and made of, for example, 2-0, 3-0, or 4-0 Prolene
30 17 (commercially available from Ethicon) or nylon, may be attached to the proximal end of
18 the contralateral leg of the Y-shape stent. This monofilament may be connected firmly to
19 the proximal portion of wire 230 that secures the contralateral leg of the stent.

35 20 In operation, both femoral arteries may be punctured and adequately-sized
21 introducer sheaths inserted in each. From the left femoral approach, a first nitinol snare
22 e.g., an Amplatz Gooseneck snare (commercially available from Microvena), may be
40 23 inserted and manipulated into the right iliac artery. From the right femoral approach, a
24 second nitinol snare similar to the first (e.g., Amplatz Gooseneck from Microvena) may
25 be inserted by which the first nitinol snare may be pulled through the right femoral
26 sheath. While the stent 10 remains still outside the body, monofilament 250 and wire
45 27 230, both of which are attached to the contralateral leg of the stent 10, may then be pulled
28 through the left femoral sheath by the first nitinol snare.

5
1 The delivery system 200 may then be inserted through the right femoral sheath
2 and positioned in the abdominal aorta so that the contralateral leg 30 of the stent 10 can
3 be above the aorto-iliac bifurcation. Pulling back monofilament 250/wire 230 together
10 4 with the whole delivery system, the contralateral leg 30 of the stent 10 may be positioned
5 in the left iliac artery.

6 As the first step of deployment, wire 230, which secures the contralateral leg of
15 7 the stent, may be pulled out so that the contralateral leg will be released first. Pulling on
8 the monofilament 250, tube 210 may be removed through the left femoral artery sheath.
9 The ipsilateral leg 30 of the stent 10 may be released by withdrawing the third wire 270.
20 10 In the next step of delivery, the common body 20 of the stent may be released after
11 pulling nitinol wire 240 out. In the final step, the longer tubing of the delivery system
12 200 may also be withdrawn and removed through the right femoral sheath. It is to be
13 understood that the order of release of the legs and common body of stent 10 may differ
25 14 from that just described.

15 In an exemplary embodiment of delivery system 200 according to the present
16 invention, multiple securing wires may be used to form small profile loops instead of only
30 17 one for each leg and the common body of the stent (i.e., 240, 230 and 270). In such an
18 embodiment, the wires may be formed with tapered ends so as to reduce the possibility of
19 a crowded arrangement of securing wires and closed structures. It is also to be
35 20 understood that in an exemplary embodiment of delivery system 200 according to the
21 present invention, a single securing wire such as 240, 230 or 270 may be threaded back-
22 and-forth through multiple pairs of holes so as to form multiple small profile loops for
23 securing more than one closed structure of a given portion of the stent. In such an
40 24 embodiment, the wire may be tapered for the same reason earlier given. It is to be
25 understood that any combination of the two embodiments above may be utilized. Thus, 2
26 or more securing wires (which may be tapered) may each be threaded back-and-forth
45 27 through multiple pairs of holes, while one securing wire may be threaded through only
28 one pair of holes, etc.

5 1 The aorto-iliac type of delivery, which may use two access sites, may be used for
2 2 placement of bifurcated stents in the biliary system or in hemodialysis grafts.

10 3 The present invention thus permits an advantage anywhere there is a bifurcated
4 4 anatomical structure. This invention comprises a coherent element that can maintain all
5 5 three lumens forming the Y-shape. A stent according to the present invention formed
6 6 from one contiguous main body and two legs may eliminate all possible problems
15 7 associated with Y-shaped stentings using separate stents. Separate stents need to be
8 8 positioned in close apposition to each other to form the best possible seal and prevent
9 9 tumor invasion (provided a covered stent is used) (Peterson, 1995). If any T, Y or V
20 10 shape configurations are achieved with separate stents, the angled portion of the tubular
11 11 structure remains the weakest.

12 12 Stents which are commonly used for the creation of a complex configuration
25 13 (such as the WALLSTENT and the Gianturco Z-stent) show lower than expected
14 14 expansile force when they are arranged side-by-side. According to the inventors' *in vitro*
15 15 measurements, the expansile force of two WALLSTENTS and two Z-stent, respectively,
16 16 positioned side-by-side were lower than those measured at the center of a same-size
30 17 single WALLSTENT and a Z-stent, respectively (Tables 2 and 1). The stent according to
18 18 the present invention showed the most expansile force, even at the level of the bifurcation
19 19 (Table 3). In asymmetrical side-by-side arrangement of two WALLSTENTS, the
20 20 behavior of the free ends of the partially compressed stent poses an additional concern
35 21 considering the damage free ends may do.

22 22 Except for isolated tracheal and/or bronchial lesions, self-expanding metal stents
40 23 have not been used to maintain the lumen of the bifurcations. Apart from stent-grafts,
24 24 which are widely used for treatment of abdominal aortic aneurysms, only the Dynamic
25 25 tracheo-bronchial stent has been made as a bifurcated stent (Freitag, 1994).

45 26 In selecting the proper size of the bifurcated stent, one should take into account
27 27 the different diameters of the vessel at both the proximal and the distal ends of the stent.
28 28 Ideally, the best possible matching between the diameters of the vessel and the stent

5
1 would result in a wedge-effect. This wedge effect may be utilized to fix the stent within
2 the vessel, preventing distal migration and possibly reducing intimal hyperplasia induced
3 by a pressure that is higher than ideal. In a comparative experimental study, it turned out
10 4 that of the Palmaz stents, WALLSTENTS and the Memotherm nitinol stents, none
5 appeared to be preferable to the others regarding neointimal formation in the short- to
6 mid-term follow-up period (Schurmann, 1996). At this time, the advantage of using a
15 7 flexible vs. a rigid stent, or whether a balloon-assisted deployment is more advantageous
8 over a self-expanding delivery mechanism with regard to preventing the production of
9 intimal hyperplasia has not been established. As for a nitinol bifurcated stent, a possible
10 flared proximal end of the stent may further improve the fixation of the stent if it is
20 11 necessary.

12 The following general description may further provide one with guidance in
13 selecting an appropriately sized stent. The stent may be inserted into the body in a
25 14 completely elongated state. When the stent is allowed to assume its unconstrained size
15 and shape, it may be significantly shortened. As the stent is first shortened, a small
16 decrease in length may result in a relatively large increase in stent diameter. As the stent
30 17 approaches its completely unconstrained state, however, this relationship is less
18 pronounced, and a proportionate decrease in length may result in a much smaller increase
19 in diameter. As a result, if a stent leg or common body with a diameter of 12 mm is
20 deployed in a vessel with a diameter of 10 mm, that leg or common body may remain
35 21 significantly elongated. This characteristic, though, may be advantageous if the tissue of
22 the vessel is flexible. Data gained with other stents (*e.g.*, Z-stent) have shown that the
23 wall of a tubular structure (vessel, biliary tree, *etc.*) is readily, gradually, and quickly
40 24 dilated and the stent is able to assume its unconstrained size within hours to days.

25 In the inventors' tracheobronchial study, described in the Example below, the
26 inventors observed that both the stent legs and the common body changed in diameter and
45 27 length even two weeks after stent placement.

28 The present invention may also be used in the treatment of aneurysms. The
29 successful treatment of an aortic aneurysm "either abdominal (AAA) or thoracic (TAA)]

5
1 depends on completely excluding it from the circulation. Therefore, incompletely fixing
2 a stent-graft may result in persistent flow within the aneurysm sac. These perigraft leaks,
3 also called endoleaks, can occur because of incomplete fixation at the proximal and distal
10 4 ends. Endoleaks complicate between 8-44% of endovascular AAA repairs. There is
5 experimental and clinical evidence that endoleaks can cause aneurysm rupture (Bakal,
6 1998).

15 7 **Abdominal Aortic Aneurysm Treatment**

8 Short infrarenal necks (< 2 cm) may increase the risk of a proximal endoleak. In
9 these cases, deploying the proximal fixation stent, typically a Z-stent, of an endovascular
20 10 graft in the juxtarenal rather than in the infrarenal aorta can potentially prevent a proximal
11 leak. The bare portion of the anchoring stent is placed across the renal arteries, with the
12 covered portion beginning at the infrarenal level. Serious concern remains that any
25 13 proximal dislodgment of the stent-graft (due to endoluminal migration and/or to
14 shrinkage of the aneurysm) may threaten with occlusion of the renal artery(ies).

15 AAAs with non-short infrarenal necks may also be treated by placement of a
30 16 covered bifurcated stent-graft. The covering material should be thin and stretchable
17 enough to be able to follow the movements of the weave. The possible covering
18 materials include woven Dacron, non-thrombogenic polyurethane, ultrathin and
19 somewhat elastic PTFE, polyester (commercially available from Tetko Inc. in Briarcliff
35 20 Manor, NY), and any other suitable materials that are biocompatible and may follow the
21 movement of the weave of the stent. Woven Dacron may be coupled to the stent using
22 polypropylene monofilament sutures. In one embodiment, it may be coupled to the stent
40 23 using 5-0, 6-0, or 7-0 sutures (Ethicon). Ultrathin and somewhat elastic PTFE may be
24 coupled to the stent in the same manner as the woven Dacron. Nonthrombogenic
25 polyurethane may be coupled to the stent using glue or heat. In other embodiments,
26 Teflon or silicon compounds may be coupled to the stent using any suitable means above
45 27 described.

5
1 Using a stent according to the present invention, a covered trifurcated stent may
2 be created. In this embodiment of the invention, the stent 300 has a common body 310
3 and two legs 320 (FIG. 7). The common body 310 (or suprarenal trunk) of the stent 300
10 4 will be placed into the lumen of the abdominal aorta, whereas the legs 320 are placed into
5 the main renal arteries. The third leg 305 (or infrarenal trunk) will also be placed in the
6 abdominal aorta, but it will be located below (or caudad) of the renal arteries. Although
15 7 an appropriate portion of the stent 300 depicted in FIG. 7 may be covered, this covering
8 is not shown for the sake of clarity. According to this embodiment, the lumen of the
9 juxtarenal portion 331 of the aorta 312 together with those of the renal arteries 313 should
10 be maintained first with the trifurcated stent-graft (FIG. 8, again, the graft material is not
20 11 shown for the sake of simplicity), then another covered stent-graft (a straight tube graft or
12 a bifurcated stent-graft) may be positioned into the distal abdominal aorta. The two
13 stent-grafts should then be anastomized to each other, creating a completely sealed
25 14 endograft. To achieve a good contact/connection between the two stent/stent-grafts with
15 an appropriate seal, the straight tube stent or the common body of the bifurcated stent
16 may be preferably flared.

30 17 The potential advantages of this embodiment include: (1) the shortness of the
18 proximal aortic neck of the aneurysm will not be a limiting factor in selecting patients
19 suitable for endovascular repair of stent-grafts; (2) the potential hazard from distal
20 embolization and/or occlusion of the renal arteries can be eliminated; and (3) complete
35 21 exclusion of the aneurysmal sac can potentially be achieved because the stent-graft will
22 be anchored in the intact suprarenal portion of the aorta.

40 23 The weaving for this embodiment is similar to that which is used to create a
24 bifurcated stent according to the present invention. To produce the trifurcated version,
25 the weaving process should be started on three templates as above described. According
26 to the inventors' studies, a minimum of 4 wires may be used to form the smaller (renal)
45 27 legs 320 of the stent. The common trunk 310 of the stent, where all the wires are used for
28 weaving the stent structure, may be formed with the largest diameter. This portion of the
29 stent will be placed more cephalad (suprarenally, or, in other words, closer to the head)

5 1 into the aorta. The weaving may be started on the two legs and the common trunk in
2 2 separate stands. As in the case of the bifurcated stent, the templates for the legs may then
3 3 be joined with the template of the common trunk as shown in FIG. 27A, and the plain
10 4 weaving may be continued as above described and shown in FIG. 27B. The assembly
5 5 may then be heated and cooled as described above, and reshaped and reheated as
6 6 described above as needed.

15 7 The trifurcated stent may be delivered in the following manner. The delivery
8 8 system depicted in FIG. 6 may be modified using the same materials described above to
9 9 include a third tube such that both legs and both the lower and upper portions of a
20 10 common trunk may be secured to tubes in the manner above described. The stent may
11 11 then be so secured. Then, a right femoral artery access may be established by placing an
12 12 introducer sheath in it. Two steerable guidewires may then be inserted from a cranial
13 13 approach (from an axillary, brachial, or carotid artery) into the aorta. Using a foreign
25 14 body retrieval device (preferably a snare), both of them may be pulled through the right
15 15 femoral artery access. Each of the guidewires may be pulled through the lumen of the
16 16 stent legs still outside the body. The stent may then be inserted and advanced into the
30 17 abdominal aorta over a third guidewire placed into the lumen of the delivery system.
18 18 From the cranial arterial access, a guidewire may be placed into each renal artery. The
19 19 stent's proper orientation may be facilitated by placing markers on the dedicated portion
20 20 of the stent. The guidewires should preferably be marked as right and left on their
35 21 segments which are outside the body so that one can avoid twisting the stent. Once both
22 22 renal wires are in place, the securing nitinol wires used to hold the stent legs to the
23 23 common body as well as to the delivery system may be released one by one. In the final
40 24 stage of the procedure, the securing wires holding the common body of the stent may
25 25 also be released.

26 **Thoracic Aorta Aneurysm Treatment**

45 27 The thoracic aortic aneurysm (TAA) can be treated by less invasive endovascular
28 28 strategies for patients considered at high risk for conventional surgery. Using the
29 29 stent-grafts currently available for this purpose, the aortic neck proximal and distal to the

aneurysm must have a diameter ≤ 40 mm and a length ≥ 15 mm (Semba, 1998). Shorter proximal necks cannot be safely treated with a stent-graft because of the potential occlusion of the left subclavian artery. The positioning of the proximal anchoring stent of the stent-graft across the left subclavian artery offers a possible alternative to eliminate this problem. Deployment of another stent into the left subclavian artery to maintain its lumen is another possibility. Both solutions, however, carry some risk of distal embolization and arterial occlusion.

As shown in **FIGS. 9 and 10**, a bifurcated stent-graft **500** according to the present invention having a smaller caliber leg **510** for the left subclavian artery and a larger trunk **520** for the aortic lumen may solve the problem. This stent-graft effectively seals the lumen of the aneurysm and simultaneously maintains the patency of the subclavian artery. For the sake of simplicity, the graft materials that may be used to cover all or part of the stents of stent-grafts **500** are not shown in **FIGS. 9 and 10**. Stent-graft **500** depicted in **FIGS. 9 and 10** will be understood to have a first leg, leg **510** for example, a second leg, trunk **520** for example which resides in aorta **312** as illustrated in **FIG. 10**, and a common body having a portion **511** that is proximate portions of both leg **510** and trunk **520**, and which is formed from the wires forming both leg **510** and trunk **520**. **FIG. 10** depicts a delivered stent-graft **500**.

Stent graft **500** may be formed using plain weave as described above, and may be delivered using the Aorto-Iliac Application delivery system above. The concept of maintaining the lumen patency of the larger branches of the aorta adjacent to the aneurysm with the same stent-graft used to treat the aneurysm itself may be utilized to solve the most frequent and serious problems currently associated with endografting of AAA and TAA.

Aortic Arch Reconstruction

One or more of the present bifurcated stents may be used for reconstruction of the aortic arch. If the disease affects both the aorta and one or more large vessels (such as the brachiocephalic, left carotid or left subclavian artery) the treatment utilized should be

5 -
1 designed to maintain the aortic lumen without compromising the blood flow in the side
2 branches. The underlying pathological condition (such as an aneurysm) may require that
3 the treatment involve the use of a stent-graft in order to exclude the aneurysmal sac from
10 4 the circulation by creating a new lumen. This treatment is depicted in one embodiment in
5 FIG. 10, which shows treatment of the TAA with a bifurcated stent-graft (although the
6 cover material is not shown) according to the present invention.

15 7 In other cases involving the stenosis of large arteries (e.g., the subclavian, and the
8 common carotid arteries) along with that of the aorta, the aortic lumen can be
9 reconstructed using combinations of uncovered bifurcated stents. FIGS. 20-22 depict the
10 aortic arch 313, the left subclavian artery 314, the carotid artery 316 and the right
20 11 subclavian artery 317. FIG. 20 also depicts two bifurcated stents: the first of which,
12 bifurcated stent A, may be delivered using delivery system 200 depicted in FIG. 6 in the
13 manner described above. After bifurcated stent A is delivered, bifurcated stent B (the
25 14 second of the two) may be delivered using the same delivery system and in the same way.
15 As depicted in FIG. 20, the two bifurcated stents may be delivered such that A overlaps
16 B somewhat. The weave of bifurcated stent B is not depicted in FIG. 20 for the sake of
30 17 simplicity of illustration.

18 FIG. 21 depicts three bifurcated stents, A, B, and C, delivered in the same manner
19 as the two bifurcated stents depicted in FIG. 20, and with the same type of overlap. In
20 some situations, a combination of a bifurcated stent-graft and a stent-graft that is formed
35 21 using the weaving methods disclosed herein, but that is straight, may also be used. Thus,
22 the doctor is free to utilize any combination of stents to achieve his or her purpose.

40 23 The extent to which the current bifurcated stents are covered may be varied
24 according to the treatment method needed. As shown in FIG. 22, the portion of trunk
25 520 (which occupies the portion of aortic arch 313 downstream of left subclavian artery
26 314, and which is designed to seal aneurysmal sac 318) is covered, while leg 510, which
45 27 occupies left subclavian artery 314, and the portion 511 of stent 500, which is positioned
28 upstream of left subclavian artery 314 are uncovered.

5
1 This embodiment may be advantageous when the thoracic aortic aneurysm affects
2 the segment of the aorta immediately surrounding the orifice of left subclavian artery 314,
3 or in other words, when the cephalad neck of the aneurysm is very short. In this situation,
10 4 the use of a straight stent-graft (that is, a non-bifurcated stent-graft) is controversial
5 because the shortness of the cephalad neck of the aneurysm virtually eliminates the
6 possibility of safely and adequately achieving fixation of the straight stent-graft without
7 compromising blood flow in left subclavian artery 314. Using the embodiment of the
15 8 present invention depicted in FIG. 22, however, uncovered leg 510 is designed to
9 maintain the patency of left subclavian artery 314 while the covered portion of trunk 520
10 should effectively seal aneurysmal sac 318, thereby preventing endoleak from left
20 11 subclavian artery 314. If left subclavian artery 314 suffers from aneurysmal dilation, a
12 completely covered bifurcated stent-graft should be used. Either embodiment – partially
13 or completely covered – may be delivered using delivery system 200 as described above.

25 14 **Aorta and Bilateral Renal Artery Replacement Using Two Bifurcated Stents**
15 15 **Positioned Side-By-Side**

16 As shown in FIG. 40, two bifurcated stents 10 (stent-grafts, not shown, may also
30 17 be used) are used side-by-side in aorta 312, and renal arteries 313. In this embodiment,
18 the bifurcated stents 10 (or bifurcated stent-grafts 500, not shown) may be secured to two
19 delivery systems 200 and delivered as described above. They may be released
20 simultaneously so as not to allow either to expand at the expense of the absence of the
35 21 other. In one embodiment, each trunk occupies about 50% of the intraluminal space
22 available in the aorta.

40 23 The use of two uncovered bifurcated stents as just described is warranted if the
24 abdominal aortic aneurysm has a short proximal neck (that is, one that extends only
25 slightly upstream of the renal arteries) that makes it virtually impossible to use stents
26 having a graft material that would block renal circulation. Depending on the length of the
45 27 aneurysmal neck and/or the possibility of endoleak from the renal arteries, the renal legs
28 of the bifurcated stent may be covered or uncovered. If the renal circulation would not be

1 compromised by covering the renal legs, the portion of the trunk located upstream of the
2 renal arteries may be left uncovered.

3 **Combined Treatment of Aneurysms Consisting of Stent Placement and**
4 **Transcatheter Embolization**

5 In one embodiment of the present invention, the bifurcated (and in some lesions
6 even the trifurcated) stent may be used for aneurysm treatment without being equipped
7 with a graft material. In this embodiment, the "naked" stent may serve as a scaffold for
8 developing an endothelial layer on the newly formed vessel lumen, while the aneurysmal
9 sac may be excluded from circulation by transcatheter embolization.

10 Generally, the stent may be delivered into place, and an embolic agent may be
11 inserted into the surrounding aneurysmal sac as shown in FIG. 30, which depicts the
12 abdominal aorta 650, the left renal artery 652, the right renal artery 654, the left iliac
13 artery 656, and the right iliac artery 658.

14 The stent may be delivered into place as above described. As shown in FIG. 30,
15 once the stent is in the appropriate position, an angiographic catheter 600 (5-French to 7-
16 French) that is chemically compatible with the embolic agent (not polyurethane when the
17 embolic agent contains DMSO) may be inserted and advanced into the lumen of the stent.
18 In advancing the angiographic catheter into the lumen of the stent, one may use the same
19 guidewire which may have been used in delivering the stent. However, one may advance
20 the angiographic catheter without the use of a guidewire. An adequately sized
21 microcatheter 610 (2-French to 4-French) that is chemically compatible with the embolic
22 agent may then be advanced through the angiographic catheter, on an appropriately-sized
23 guidewire (0.014-inches to 0.025-inches). The tip of the microcatheter may then be led
24 through the weave of the stent into the aneurysmal sac 620. If the openings in the weave
25 of the stent are approximately 2.0 to 2.5 mm, 600 may also be advanced into the
26 aneurysmal sac. An embolic agent 630 may then be inserted into the aneurysmal sac
27 through the microcatheter. Embolic agent 630 may be chosen so as to be: non-toxic, non-
28 irritant/reactive to the tissues; easily handled; suitable for continuous injection;

5 1 adequately radiopaque; capable of filling the space contiguously without leaving
2 2 unoccupied spaces; and non-fragmented, thereby not getting back through the stent's
3 3 weave into the newly formed lumen which could result in peripheral embolization.

10 4 Although several fluid embolic materials (alcohol, poly-vinyl alcohol,
5 5 cyanoacrylates, Ethibloc *etc.*,) are available for transcatheter vessel occlusion, none of
6 6 them is considered ideal or even suitable for this purpose. Recently, a nonadhesive,
15 7 liquid embolic agent, ethylene vinyl alcohol copolymer (EVAL), has been used clinically
8 8 for treatment of cerebral AVMs in Japan (Taki, AJNR 1990; Terada, J Neurosurg 1991).
9 9 The co-polymer was used with metrizamide to make the mixture radiopaque and may
10 10 serve as the embolic agent for the present invention.

20 11 Very recently, a new embolic agent (similar to EVAL), EMBOLYX E (ethylene
12 12 vinyl alcohol copolymer) (MicroTherapeutics Inc., San Clemente, California) was
13 13 developed, which was designed for aneurysm treatment (Murayama, Neurosurgery 1998),
25 14 and may be utilized as an embolic agent in one embodiment of the present invention.
15 15 The embolic agent is composed of a random mixture of two subunits, ethylene
16 16 (hydrophobic) and vinyl alcohol (hydrophilic). Micronized tantalum powder is added to
30 17 it to obtain an appropriate radiopacity, and DMSO (di-methyl sulfoxide) is used as an
18 18 organic solvent. When the polymer contacts aqueous media, such as blood, the solvent
19 19 should rapidly diffuse away from the mixture causing in situ precipitation and
20 20 solidification of the polymer, with formation of a spongy embolus and without adhesion
35 21 to the vascular wall. Any kind of material with characteristics similar to those of
22 22 EMBOLYX E may be used as an embolic agent for the present invention.

40 23 Both abdominal and thoracic abdominal aneurysms may be treated as above
24 24 described. In some other locations (*e.g.*, external iliac artery), pseudoaneurysm and/or
25 25 tumor-induced corrosive hemorrhage may also be treated as above described.

45 26 The size of the delivery system that may be used to deliver a bifurcated stent
27 27 without a graft cover may be sufficiently small, such that insertion of the stent into the
28 28 vessel may take place following a percutaneous insertion. The delivery system would

5 1 also be well-suited to negotiating through tortuous vascular anatomy. The treatment
2 described above may be performed using interventional radiology techniques, thereby
3 eliminating the need for surgery. The embolization may occlude the lumbar arteries from
10 4 which the excluded aneurysmal sac is frequently refilled. As a result of using the
5 treatment described above, the leak from the patent lumbar arteries may be eliminated.

6 The following examples are included to demonstrate illustrative embodiments of
15 7 the invention. It should be appreciated by those of skill in the art that the techniques
8 disclosed in the examples which follow represent techniques discovered by the inventors
9 to function in the practice of the invention, and thus can be considered to constitute
10 illustrative modes for its practice. However, those of skill in the art should, in light of the
20 11 present disclosure, appreciate that many changes can be made in the specific
12 embodiments which are disclosed and still obtain a like or similar result without
13 departing from the spirit and scope of the invention.

25 14 EXAMPLE 1

15 15 Materials and Methods

30 16 Below, the inventors present the results of an *in vitro* study designed to establish
17 the characteristics (*i.e.* expansile or radial force and flexibility) of the inventors' new
18 bifurcated stent design and compare these characteristics to those of the Gianturco-Rösch
19 biliary Z-stent and the WALLSTENT. In addition, the inventors also present the
35 20 inventors' preliminary results with the tracheobronchial application of the new stent in
21 the pig.

40 22 As discussed above, the self-expandable bifurcated stent according to the present
23 invention has a Y-shape (Y-stent) comprising a common main body and two legs that are
24 made as one coherent element.

45 25 The stents used for this study were made by hand weave. A wooden stand with a
26 circular plate was used for weaving the stents. One of the ends of the tubular copper
27 template was equipped with multiple holes around its circumference. The midportion of

5
1 each wire was hanged on metal pins placed through these holes and secured to the
2 template with some copper wire. A 100 gram weight was attached to each free end of the
3 nitinol wires. The template with the attached wires was then placed through the wide
10 4 central hole of the circular plate of the stand in an up-side-down position. In this
5 arrangement, the end of the template with the holes made for wire attachment faced
6 down. A central weight (approx. 600 g) was hanged on this end of the template, and the
15 7 nitinol wires with the 100 gram weights were led over the flat surface of the circular
8 plate.

9 The wire ends were evenly arranged around the circumference of the circular
10 plate. The 100 gram weights and the central weight kept the wires under tension and in
20 11 balance. The weave started with two wire ends. One of the wire ends (*e.g.*, the left one)
12 was crossed over the right one. In clockwise direction, the left wire end was crossed
13 similarly over the corresponding right one. This move was continued until the circle was
25 14 finished. The direction of the move was then reversed, and the wire crossings were done
15 counterclockwise. The tightness of the weave (*i.e.* the angle between the wires) was
16 adjusted by changing the central weight. An increase in the central weight resulted in a
30 17 looser weave (decreased angle between the wires) and vice versa.

18 After the plain weave of nitinol wires was completed on the metallic template, the
19 stent/template unit was heated to 500° C for 12-15 min. After cooling to room
35 20 temperature, the stent wires possessed superelastic properties.

21 For this *in vitro* study, Y-stents according to the present invention were made
22 using 12 0.005-inch nitinol wires (Shape Memory Applications, Santa Clara, CA). The
40 23 outer diameter of the common body and the legs was 8.5 mm and 5.5 mm, respectively.
24 The characteristics of the Y-stent were compared to a four-body Gianturco-Rösch biliary
25 Z-stent® (Cook Inc., Bloomington, IN) and a WALLSTENT (Schneider, Minneapolis,
26 MN). Each body of the Z-stent was constructed of 0.012-inch stainless steel wire with
45 27 6-bends at each end and a 12 mm outer diameter. The WALLSTENT was made of 24
28 surgical grade stainless steel alloy wires (0.006-inch) and had an unconstrained outer
29 diameter of 9.5 mm.

5
1 In addition, straight, cylindrical nitinol stents were fabricated with a uniform outer
2 diameter of 13 mm to evaluate the effect of varying the number of wires and weave
3 tightness on expansile force. Stents were constructed from six, eight, and ten 0.011-inch
10 4 super-elastic nitinol wires and the tightness of the weave was varied in two stents made of
5 six wires.

6 The expansile force of the stents was measured using the method described by
15 7 Fallon (Fallon *et al.*, 1988). Measurements made by this method are based on the fact
8 that the final radius to which the stent expands within a tubular structure (*e.g.*, a blood
9 vessel) depends on the pressure exerted by the wall of the structure on the stent. At
20 10 equilibrium, the pressure exerted by the wall on the stent is equivalent to that produced by
11 the stent on the wall. The response of the stent to external pressure can be measured by
12 using a non-elastic collar-type device placed around the stent.

25 13 An apparatus comprising a non-elastic paper strip and a tubular spring gauge with
14 a capacity of 500 g was fabricated to measure stent expansile force. One end of the
15 non-elastic paper strip was fixed and the other end was attached to the spring gauge,
16 forming a circular collar with an adjustable diameter. The stent was placed within the
30 17 collar. Pulling on the spring gauge caused uniform pressure to be exerted upon the stent,
18 thus decreasing the radius of the stent from the original value of R_0 to R . The change in
19 radius was expressed as the circumferential displacement measured in mm directly on the
35 20 paper strip. The force (measured in grams) needed to cause a 10 mm circumferential
21 displacement of the stent was used to compare the expansile force of each stent design.

22 The unit "grams" has been used herein as a measure of force. Although the
40 23 correct unit of force is the "dyne", which is equal to the mass in grams multiplied by the
24 gravitational constant, the inventors believe that the average reader will have a better idea
25 about the size of force when the associated mass unit (grams) is specified.

45 26 For the Z-stent and WALLSTENT, the relationship between the force exerted by
27 the collar and the circumferential displacement of the stent was measured at the mid-part
28 of the stent. Initially, measurements were made on a single stent and then a second

1 identical stent was placed alongside the former one and the measurements were repeated.
2 This was done to simulate two stents being placed side-by-side to treat a lesion occurring
3 at a bifurcation. Taking into account the fact that the multiple-body Gianturco-Rösch
4 biliary stents are the weakest at the point where the bodies are joined by nylon
5 monofilament suture, measurements were made at the mid-portion of the second body of
6 these stents. The Y-stent of the present invention was measured at the mid-portion of the
7 common body and at the bifurcation (junction of legs and common body). Measurements
8 were obtained 10 times on each stent and the results were averaged.

9 To establish the flexibility of the stents, the luminal diameter at the mid-portion of
10 the stent was measured while holding the stent at both ends and bending it 180° in the
11 middle. A transformation ratio was then calculated using the formula:

$$12 \quad \frac{D_0 - D_1}{D_0} \quad 13 \quad \quad \quad "1]"$$

14 where D0 is the luminal diameter of the stent before bending and D1 is the luminal
15 diameter after bending. This test was performed 10 times on each stent and the results
16 were averaged.

17 For statistical analysis, repeated ANOVA method (flexibility) as well as Student's
18 t-test and Mann-Whitney U-test (expansile force) were used.

19 *Animal Studies*

20 Fourteen of the Y-shape stents of the present invention and the corresponding
21 delivery systems were tested in the tracheobronchial systems of 9 pigs. First, the
22 inventors fabricated and used bifurcated stents, the common body of which had a slightly
23 elliptical cross-section with a larger frontal diameter (18 mm vs. their 15 mm a-p
24 diameter). The height of the common body was 10-12 mm in these stents, while the legs
25 were 2.8 - 3.1 cm-long and had a diameter of 9 mm.

26 A bifurcated delivery system was constructed from two 7-F Teflon tubings. A
27 piece of a 14-F thin-walled Teflon sheath was pulled over the proximal halves of these
tubings to hold them together. After gaining some experiences with the delivery system,

5 1 the inventors covered the 7-F tubings in a longer segment, leaving free only the distal
2 2 15-17 cm of the tubings (which length corresponded with the totally stretched length of
3 3 the stents). Four pairs of holes were made close to the end of each 7-F tubing and were
10 4 arranged evenly around the circumferences of the tubings. The distance between the
5 5 corresponding holes of each pair was about 4-5 mm. Two other pairs of holes were also
6 6 made on the same tubing approximately 14-16 cm away from the distal holes. 0.009-inch
15 7 superelastic nitinol wires were used to secure the stent's ends to the delivery system.
8 8 First, four securing nitinol wires were placed through the lumen of one of the 7-F tubings.
9 9 These wires were placed into the lumen through the proximal holes positioned close to
10 10 the distal end of these tubings. One of the legs of the bifurcated stent was pulled over the
20 11 7-F Teflon tubing and the four prepared superelastic nitinol wires were led through the
12 12 stent mesh at its distal end. Actually, the angles made from the mid-portion of the
13 13 stent-wires were used to secure the stent to the delivery system.

25 14 The distal ends of the securing nitinol wires were then threaded through the distal
15 15 holes of each hole-pair, forming a low-profile tight nitinol wire loop between the two
16 16 corresponding holes of each hole-pair. The tight wire loops held the end of the stent leg
30 17 firmly to the tubing. The other leg of the stent was attached to the delivery system in the
18 18 same way. The stent crown was secured to the delivery system using the same technique:
19 19 altogether 4 other 0.009-inch securing nitinol wires were used (2 per tubing) to create a
20 20 steady connection between the proximal part of the stent and the delivery system. The
35 21 proximal hole-pairs created on the 7-F tubings were used for this purpose. Altogether 6
22 22 securing nitinol wires were placed in the lumen of each 7-F Teflon tubing.

40 23 The proximal ends of the securing nitinol wires were marked and separated from
24 24 each other, forming two bunches of wires within each 7-F tubing: two of them were used
25 25 for securing the stent crown, the other four to hold one of the legs of the stent. A
26 26 0.018-inch nitinol guidewire with a floppy tip (Microvena Corp.) was placed in the lumen
45 27 of each tubing. The guidewires were able to move freely without interfering with the
28 28 movement of the securing wires and vice versa.

1 The stents were deployed through an 8 mm or 8.5 mm diameter tracheal tubing
2 under fluoroscopy. In the first stage of the delivery, the inventors cannulated the main
3 bronchi with the nitinol guide wires. Once the right position of the guidewires was
4 achieved, the legs of the delivery system were advanced over the guide wires until the
5 bifurcation of the stent was caught by the carina. At this point, the stent crown was
6 released by pulling back the two securing nitinol wires in each 7-F tubings. Immediately
7 after that, the stent's legs were released by withdrawal of the 4 securing nitinol wires on
8 each side. The delivery system was then removed from the tracheobronchial system.

9 RESULTS

10 Part 1: *In vitro* Study

11 *Expansile Force*

12 The cumulative data from the measurements of the stents' expansile force is
13 summarized below in Tables 1, 2 and 3 below. In each table, the designation Δ in the
14 leftmost column of each table represents the circumferential displacement (in mm) of the
15 stent in question. For example, a Δ of 2 mm indicates that the circumference of the stent
16 in question was reduced by 2 mm, and the force necessary to effect that displacement was
17 then recorded.

18 Table 1 – Z-Stent, 6 Bends, Caliber: 12 mm

Δ (mm)	Body Center	Between Bodies	Side By Side
2	16	13	19
4	36	28	31
6	51	44	42
8	63	61	56
10	81	79	62
12	100	98	76
14	115	119	90
16	127	133	101
18	146	192	122
20	165		142

Table 2 – WALLSTENT 0.006" diameter wire, 24 wires

Δ (mm)	Center	Overlap	Side by Side
2	15	35	18
4	25	59	22
6	42	80	35
8	50	108	42
10	60	126	48
12	74	149	54
14	84	170	63
16	100	197	73
18	111	220	84
20	129	248	96

Table 3 Y-Stent, 0.005" nitinol wire, 12 wires,
caliber: trunk - 8 mm, branch - 5mm

Δ (mm)	Trunk	Junction
2	44	51
4	91	109
6	126	143
8	158	155
10	167	164
12	175	191
14	184	
16	202	

The force (measured in grams) needed to cause a 10 mm circumferential displacement of a single four-body Z-stent was 81 g, and 62 g was required for two four-body Z-stents placed side-by-side ($p < 0.0001$). For the WALLSTENT, 60 g and 48 g were needed, respectively ($p < 0.0001$). The values for the common body and the bifurcation of the Y-stent were 167 g and 164 g, respectively. These results indicate that the expansile force of a nitinol Y-stent constructed according to the present invention from 12 0.005-inch nitinol wires is greater than the force exerted by a 6-bend Z-stent fabricated from 0.012-inch stainless steel wire or a WALLSTENT made of 24 stainless

1 steel alloy wires (0.006-inch). The bifurcated stent exhibited significantly greater
2 expansile force than the Z-stent or WALLSTENT ($p < 0.0001$). The expansile forces
3 measured at the common body and the bifurcation of the Y-shape stent were almost
4 identical ($p < 0.0092$).

5 *Stent Flexibility*

6 The four-body Gianturco-Rösch biliary Z-stent started to lose its lumen in the
7 mid-portion of the stent at an angle of 40°. The lumen collapsed completely at 90-100°.
8 When the WALLSTENT was bent, the luminal diameter increased from 9 mm to an
9 average diameter of 12.0 mm (range: 11.5 - 13.0 mm) at a bend of 180°. This means the
10 transformation ratio was 33.3% (range: 27.7% to 44.4%). However, the stent shortened
11 at the same time the luminal diameter increased. When the common body of the Y-stent
12 of the present invention was bent 180° in the middle, the luminal diameter decreased
13 from 8 mm to an average of 7.3 mm (range: 7.5 - 7.0 mm). The transformation ratio for
14 the Y-stent was 8.75% (6.25 - 12.50%). The stent did not shorten during bending. The
15 flexibility of the Y-shape stent was superior to both the Z-stent and the WALLSTENT
16 ($p < 0.0001$).

30 **Part 2: Animal Evaluation**

18 The stent placement was technically successful in 9 of 14 cases. Delivery system
19 failure resulted in premature deployment (2 cases), twisting of stent legs during
20 deployment (2 cases), and inability to release stent legs (1 case). Five stents migrated
21 because the unconstrained stent diameter was smaller than the tracheobronchial system.
22 Three of them were removed one week after stent delivery because of significant
23 discrepancy between the size of the stent and the tracheobronchial system. Persistent
24 cough occurred in 3 pigs because the stent legs were longer than the main-stem bronchi
25 which resulted in distal bronchi placement.

45 26 Three animals were followed up for 8 wk, one animal for 4 wk after stent
27 placement. All these stents remained patent, there were no pulmonary lesions related to
28 the presence of the stents. These animals tolerated the stent well.

DISCUSSION

Due to the characteristics of nitinol wire, the Y-stent of the present invention can be stretched into low profile and deployed using its superelasticity. Therefore, after inserting the stent at the lesion, the stent should readily recover from its constrained state and a balloon catheter should not be required. The unique contiguous weave of the design makes it possible to achieve virtually complete coverage of a lesion occurring at a bifurcation without gap formation. Therefore, it might be possible to use a single stent according to the present invention to treat this type of lesion, whereas now it requires special techniques and the placement of multiple stents.

In the present *in vitro* study, the Y-stent of the present invention demonstrated greater expansile force than the Z-stent or WALLSTENT. This study showed that two Z-stents or two WALLSTENTS positioned side-by-side exhibit lower radial force than a single stent of each type ($p < 0.0001$). Therefore, the rationale for using Z-stents or WALLSTENTS positioned side-by-side is questionable.

There are many factors that influence the characteristics of a stent made by using a simple weave pattern such as the Y-stent and the WALLSTENT. The size and the number of the wires used to form the mesh, the angle created between the wires, and the shape memory properties of the wire will determine the physical properties of the tubular prosthesis. Therefore, stents of similar luminal diameter that possess completely different expansile force may be produced by altering the size and/or the number of the wires and the tightness of the weave.

Increasing the number of wires or the tightness of the weave can further increase the stent's radial force. It is well known that the angle between the wires of a stent, which is produced by plain weave (e.g., WALLSTENT), should preferably be greater than 90° (Wallsten, 1987). The greater the angle between the wires, the greater the expansile force of the stent. These characteristics, along with the excellent shape memory of nitinol wire make it possible to produce a Y-stent with a high radial force. A Y-stent

1 having high expansile force may help treat rigid strictures, such as those caused by scar
2 tissue formation or malignant tumors.

3 Stent diameter and wire-angle are also closely related. By increasing the angle
4 between the wires, the inner diameter of the Y-stent increases, and inversely, by
5 decreasing the wire-angle, the stent's inner diameter decreases and the stent elongates.
6 This characteristic may be utilized for production of a wide variety of woven nitinol
7 stents simply by re-adjusting the wire-angle and then re-heating the nitinol mesh. As a
8 result, the weave, radial force, diameter, length, and shape of the nitinol stent can be
9 secondarily modified after completing the primary weaving and heating processes. In the
10 case of the WALLSTENT, the physical properties are imparted to the stent during the
11 weaving process, and they cannot be changed later.

12 In addition to exhibiting a greater expansile force, the woven nitinol straight-stent
13 and Y-stent demonstrated good flexibility. These features may allow these stents to be
14 deployed in a tortuous curved structure while maintaining their luminal diameter and
15 preventing the lumen from collapse, which may occur with the Z-stent.

16 The WALLSTENT and Y-stent reacted differently to 180° bending at their
17 mid-portion. The inner diameter of the WALLSTENT increased, the wire mesh
18 tightened, and the stent shortened, whereas the inner diameter, wire mesh, and length of
19 the Y-stent remained virtually unchanged. The different behavior of the two stents can be
20 in part ascribed to the closed structures of the woven nitinol stent.

21 The closed structures of the Y-stent are also an advantageous feature for stent
22 delivery. These closed structures, created by bending the stent wires at about their
23 mid-portions, as well as by using multiple twists or other means to couple the free ends of
24 the stent-wires, allow for both ends of the stent to be secured to the delivery catheter.
25 Using a delivery system made of two coaxially placed movable tubes, the stent can be
26 repositioned even after 100% expansion prior to complete release. In addition, since the
27 stent has no sharp wire ends, potential tissue laceration and perforation can be avoided.

5
1 These preliminary *in vitro* and animal studies have shown that the Y-stent woven
2 with continuous nitinol wires has excellent self-expandable characteristics. This new
3 stent design may be useful for the treatment of both vascular and non-vascular lesions
10 4 occurring at bifurcations of tubular anatomic structures.

5 The good flexibility and high expansile force of the design may promote stenting
6 tortuous lesions as well as bridging rigid strictures resulting from scarring or malignancy.
15 7 The stent of the present invention has been developed for bifurcated and trifurcated
8 regions and may provide a new approach for solving problems in this area.

9 All of the methods and/or apparatus disclosed and claimed herein can be made
20 10 and executed without undue experimentation in light of the present disclosure. While the
11 compositions and methods of this invention have been described in terms of preferred
12 embodiments, it will be apparent to those of skill in the art that variations may be applied
25 13 to the methods and/or apparatus and in the steps or in the sequence of steps of the method
14 described herein without departing from the concept, spirit and scope of the invention.
15 More specifically, it will be apparent that certain elements may be substituted for the
16 elements described herein while the same or similar results would be achieved. All such
30 17 similar substitutes and modifications apparent to those skilled in the art are deemed to be
18 within the spirit, scope and concept of the invention as defined by the appended claims.

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- 21

Claims

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1 **WHAT IS CLAIMED IS:**

- 2 1. A device suitable for implantation into an anatomical structure, comprising:
3 a first plurality of wires defining a first leg, the first leg having a first distal
10 4 portion;
5 a second plurality of wires defining a second leg, the second leg having a second
6 distal portion; and
15 7 a common body having a distal end and a proximal portion, the common body
8 being formed from at least the first and second pluralities of wires, the
9 proximal portion of the common body being adjacent to the distal portions
10 of both legs, and both ends of at least one wire from one of the pluralities
20 11 being located proximate the distal end of the common body.
12
13 2. The device of claim 1, wherein the wires in the first and second pluralities
14 comprise nitinol.
25 15
16 3. The device of claim 1, wherein the wires in the first and second pluralities
17 comprise FePt, FePd or FeNiCoTi.
30 18
19 4. The device of claim 1, wherein the wires in the first and second pluralities
20 comprise FeNiC, FeMnSi or FeMnSiCrNi.
21
35 22 5. The device of claim 1, wherein the wires in the first and second pluralities each
23 have a diameter ranging in size from about 0.006 inches to about 0.014 inches.
24
40 25 6. The device of claim 1, wherein the first plurality of wires includes at least 6 wires.
26
27 7. The device of claim 1, wherein both the legs and the common body have tubular
28 shapes with substantially uniform diameters.
45 29
30 8. The device of claim 1, wherein at least one of the legs is hand woven.

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2 9. The device of claim 1, wherein at least one of the legs is machine woven.

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4 10. The device of claim 1, further comprising a graft material attached to at least the
5 common body.

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7 11. The device of claim 10, wherein the graft material comprises woven Dacron.

8

9 12. The device of claim 10, wherein the graft material comprises polyurethane.

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11 13. The device of claim 10, wherein the graft material comprises PTFE.

12

13 14. A stent, comprising:

25

14 a first plurality of flexible tubular strands woven to form a first leg having a first
15 distal portion, the flexible tubular strands in the first plurality crossing
16 each other to form a first plurality of angles, at least one of the angles
17 therein being obtuse;

30

18 a second plurality of flexible tubular strands woven to form a second leg having a
19 second distal portion, the flexible tubular strands in the second plurality
20 crossing each other to form a second plurality of angles, at least one of the
21 angles therein being obtuse; and

35

22 a common body having a common portion, the common body being formed from
23 at least the first and second pluralities of flexible tubular strands, the
24 common portion of the common body being adjacent to the distal portions
40 of the first and second legs.

26

27 15. The stent of claim 14, wherein the flexible tubular strands in the first and second
45 pluralities comprise nitinol.

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1 16. The stent of claim 14, wherein the flexible tubular strands in at least the first
2 plurality comprise biodegradable filaments.

3

10

4 17. A stent, comprising:

5 a first plurality of wires defining a first leg, the first leg having a first distal
6 portion;

15

7 a second plurality of wires defining a second leg, the second leg having a second
8 distal portion;

9 a third plurality of wires defining a third leg, the third leg having a third distal
10 portion; and

20

11 a common body having a proximal portion and a distal end, the common body
12 being formed from at least the first, second and third pluralities of wires,
13 the proximal portion of the common body being adjacent to the distal
14 portions of each of the three legs.

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16 18. The stent of claim 17, wherein the wires in each of the pluralities comprise
17 nitinol.

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19 19. The stent of claim 17, wherein the first plurality of wires includes at least 5 wires.

20

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21 20. The stent of claim 17, wherein each of the legs and the common body have
22 tubular shapes with substantially uniform diameters.

23

24 21. The stent of claim 17, wherein at least one of the legs is hand woven.

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26 22. The stent of claim 17, wherein at least one of the legs is machine woven.

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28 23. The stent of claim 17, further comprising a graft material attached to at least the
29 common body.

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1 24. The stent of claim 23, wherein the graft material comprises woven Dacron.

2

3 25. The stent of claim 23, wherein the graft material comprises polyurethane.

10

4

5 26. A stent comprising:

6 a first leg having a first axis and a first end, wherein the first leg comprises a first

15

7 wire having a first segment and a second segment, the segments being

8 separated by a bend in the first wire located proximate the first end of the

9 first leg, the first segment extending helically in a first direction around the

10 first axis away from the first end of the first leg, the second segment

20

11 extending helically in a second direction around the first axis away from

12 the first end of the first leg, the first and second segments crossing each

13 other in a first plurality of locations;

25

14 a second leg having a second axis and a second end, wherein the second leg

15 comprises a second wire having a first segment and a second segment, the

16 segments being separated by a bend in the second wire located proximate

17 the second end of the second leg, the first segment of the second wire

30

18 extending helically in a first direction around the second axis away from

19 the second end of the second leg, the second segment of the second wire

20 extending helically in a second direction around the second axis away

35

21 from the second end of the second leg, the first and second segments of the

22 second wire crossing each other in a second plurality of locations; and

23 a common body formed from at least one end of each of the wires.

24

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25 27. The device of claim 26, wherein the first segment of the first wire is positioned

26 farther from the first axis than the second segment of the first wire at at least one location

27 among the first plurality of locations.

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1 28. The device of claim 26, wherein the first segment of the first wire is positioned
2 farther from the first axis than the second segment of the first wire at each location of the
3 first plurality of locations.

10
4
5 29. The device of claim 26, wherein the first and second wires comprise nitinol.
6

15
7 30. A method of creating a device suitable for implantation into an anatomical
8 structure, the device having a first leg, a second leg, and a common body, each leg having
9 an end and a distal portion, the common body having a proximal portion and a distal end,
10 the method comprising:

20
11 bending the wires in a first plurality of wires to create first bent portions in the
12 wires, the first bent portions being arranged to define the end of the first
13 leg, each wire in the first plurality having two ends;

25
14 bending the wires in a second plurality of wires to create second bent portions in
15 the wires, the second bent portions being arranged to define the end of the
16 second leg, each wire in the second plurality having two ends;

17 weaving the ends of the wires in the first plurality to create the first leg;

30
18 weaving the ends of the wires in the second plurality to create the second leg; and

19 weaving the ends of the wires in both pluralities to create the common body and
20 the device;

35
21 wherein the proximal portion of the common body is adjacent to the distal
22 portions of both legs.
23

40
24 31. The method of claim 30, wherein the first bent portions are bends.
25

26 32. The method of claim 30, wherein the first bent portions are loops.
27

45
28 33. The method of claim 30, wherein the wires in the first and second pluralities
29 comprise nitinol.
30

5

1 34. The method of claim 30, wherein the wires in the first and second pluralities each
2 have a diameter ranging in size from about 0.006 inches to about 0.014 inches.

3

10

4 35. The method of claim 30, wherein the weaving the ends of the wires in the first
5 plurality is by hand.

6

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7 36. The method of claim 30, wherein the weaving the ends of the wires in the first
8 plurality is by machine.

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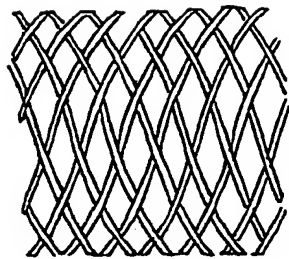


FIG. 1B

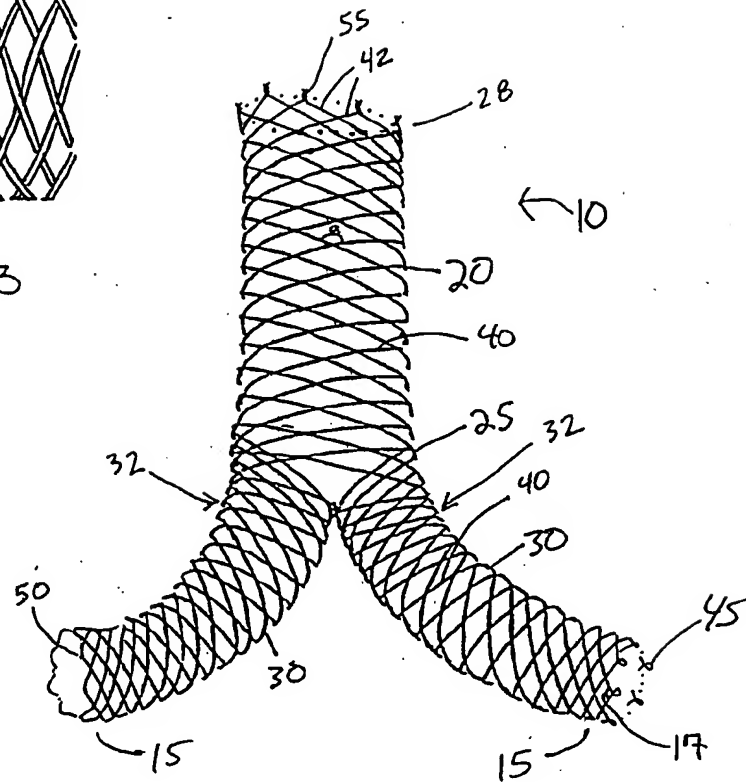


FIG. 1A

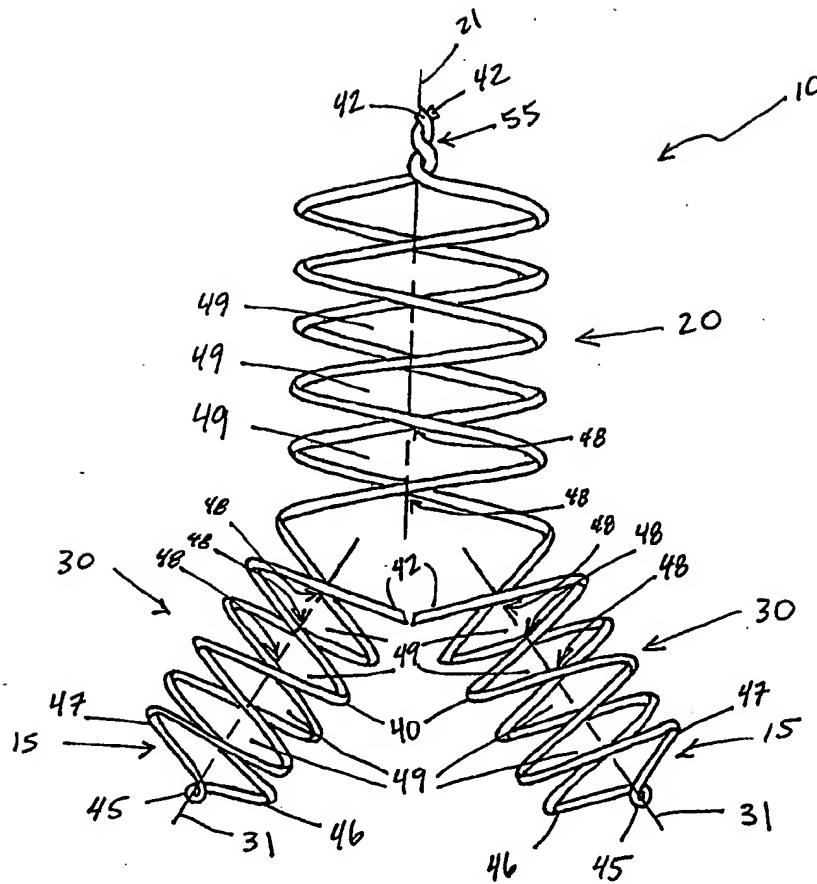
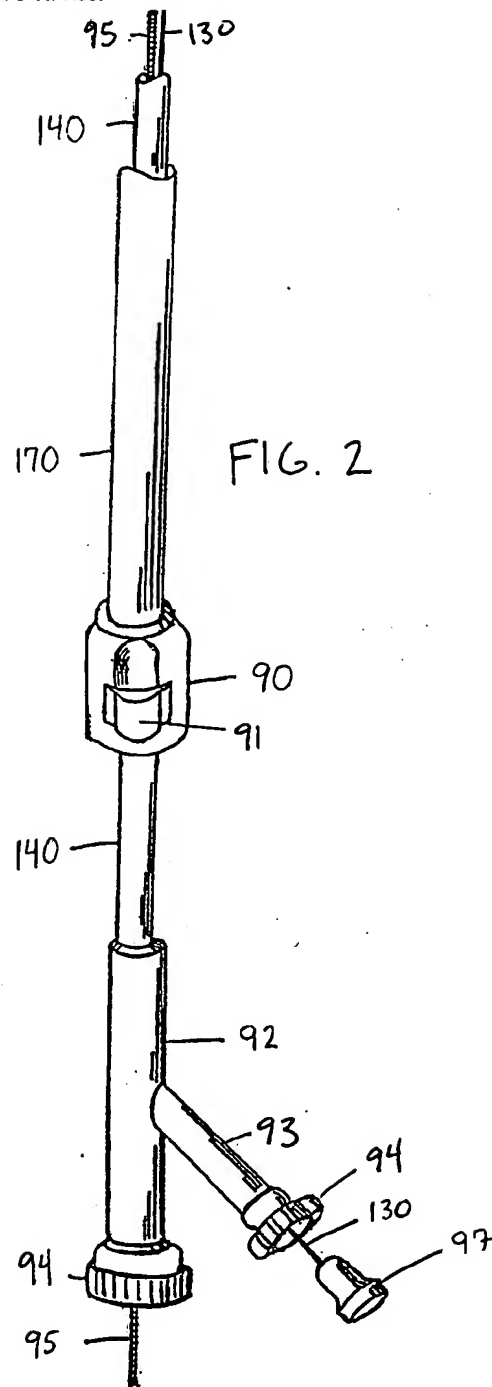
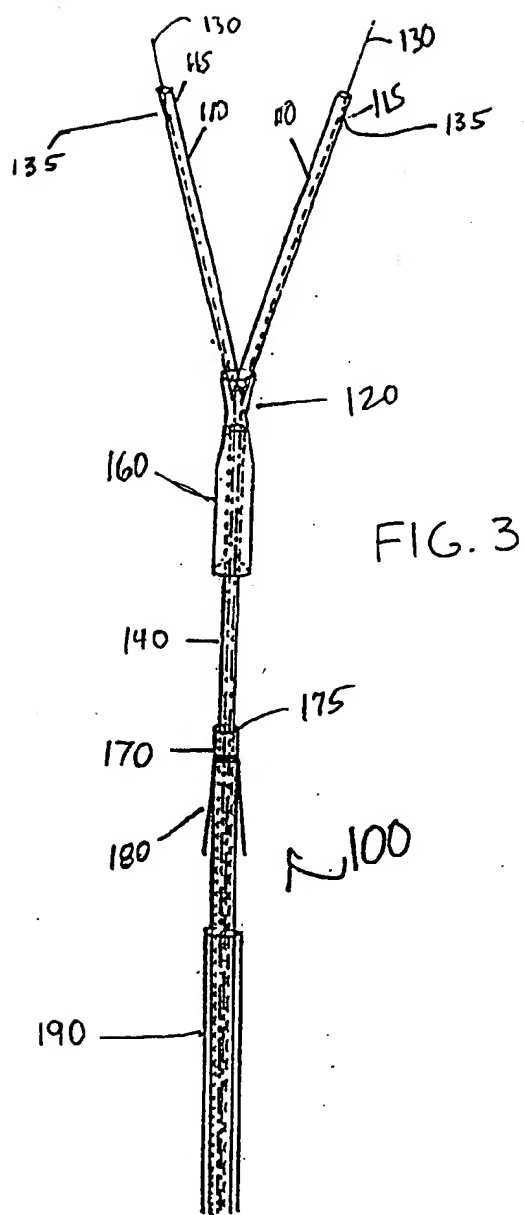


FIG. 1C





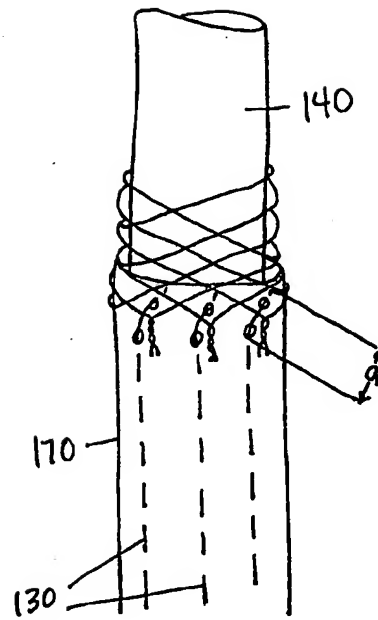
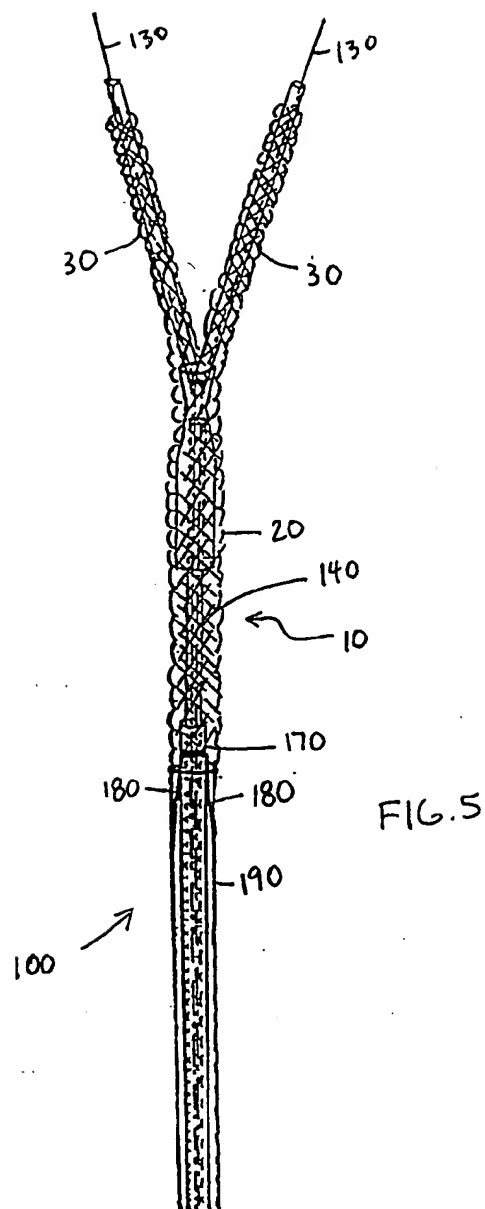
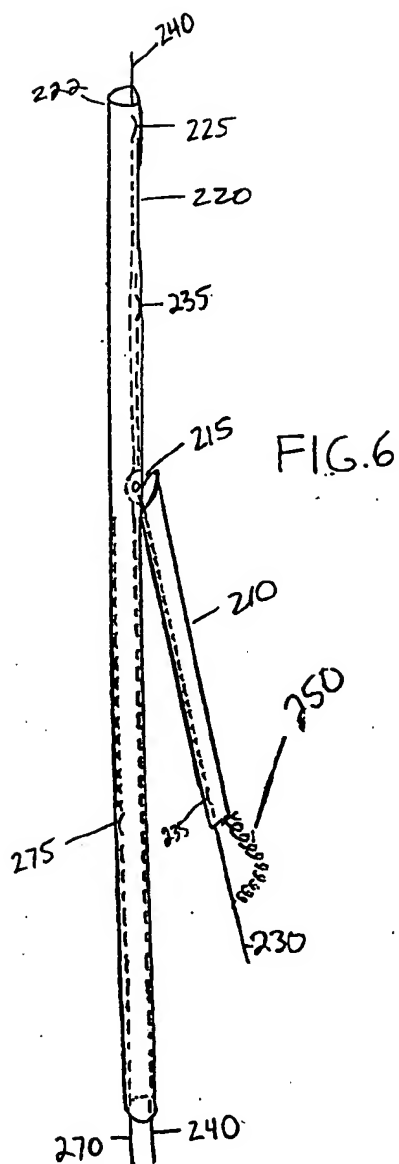


FIG. 4





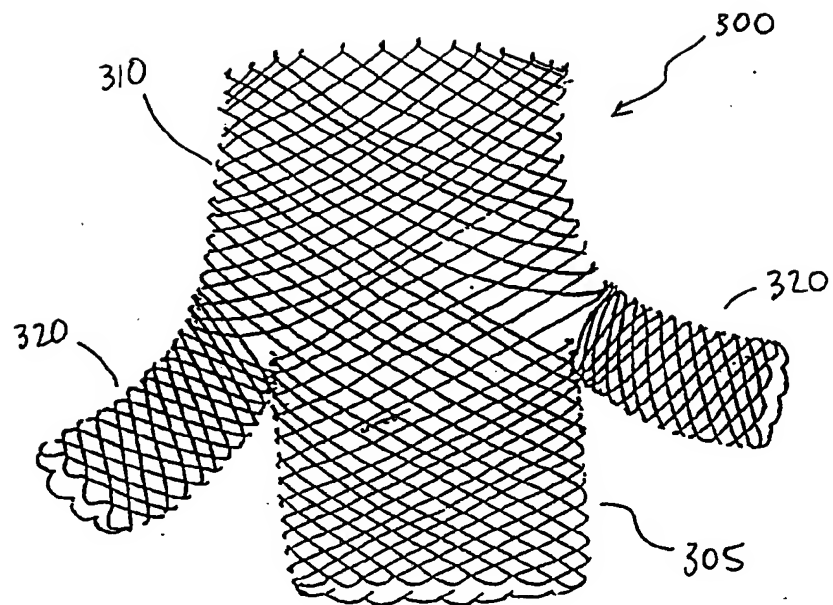


FIG. 7

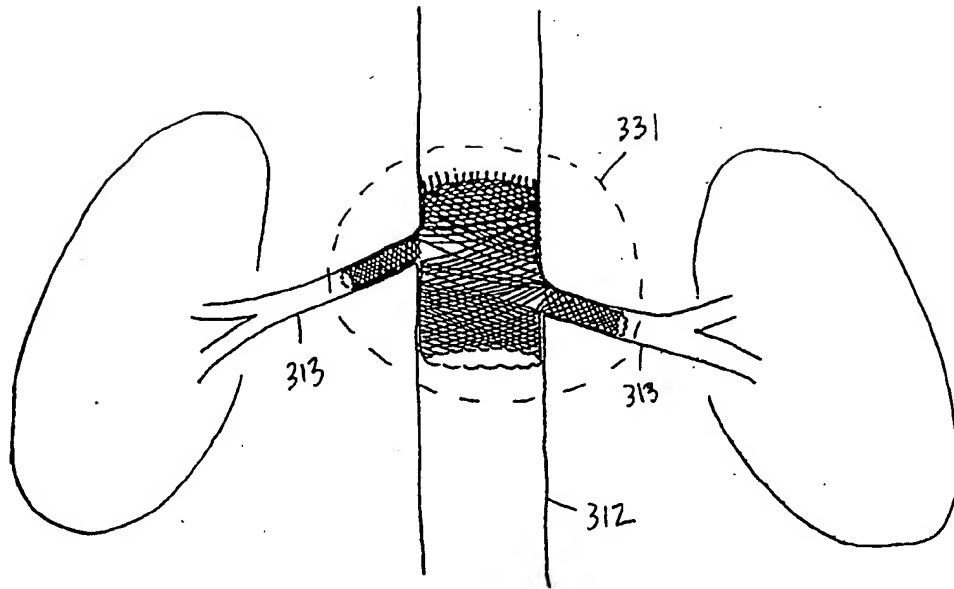


FIG. 8

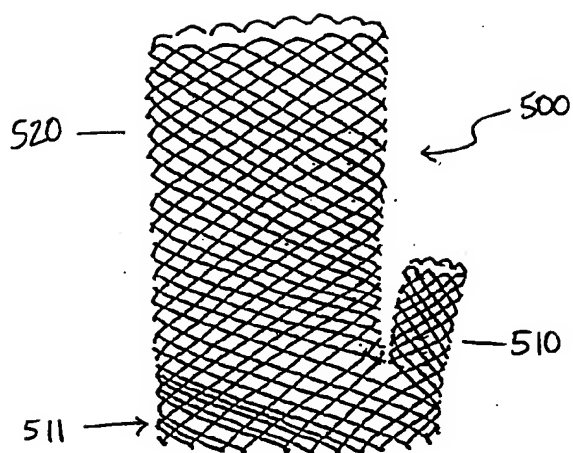
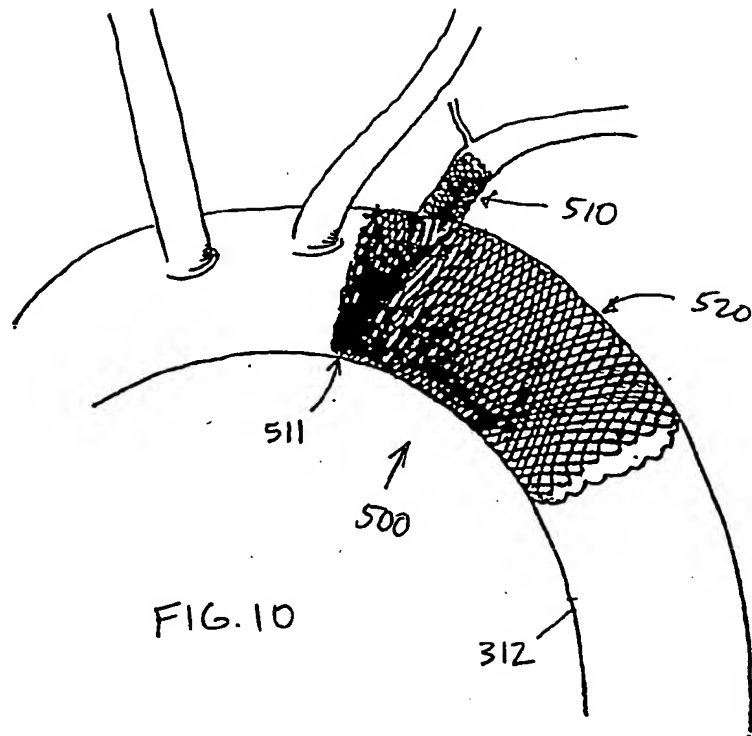


FIG. 9



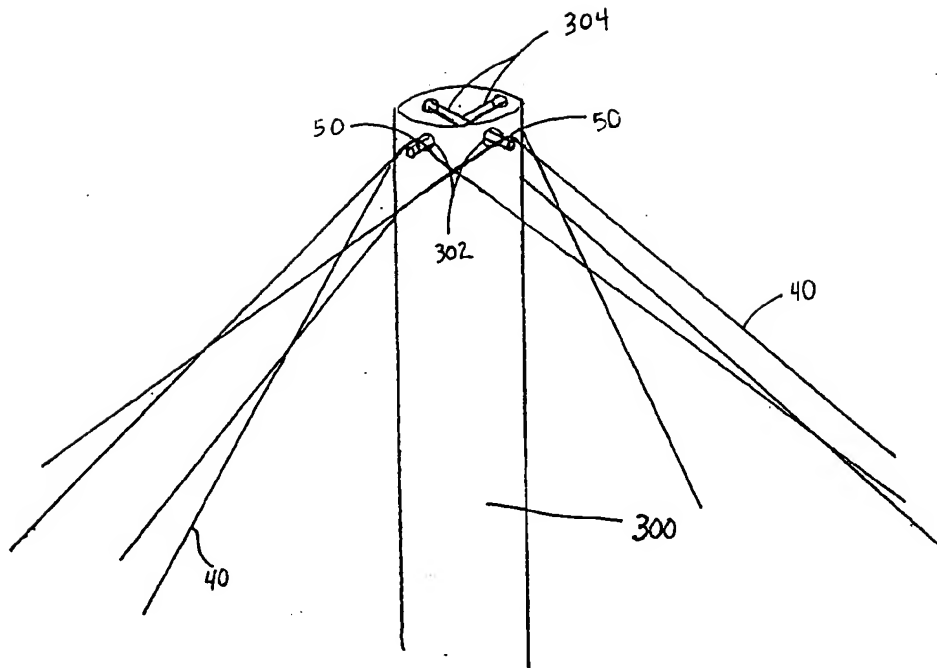


FIG. 11

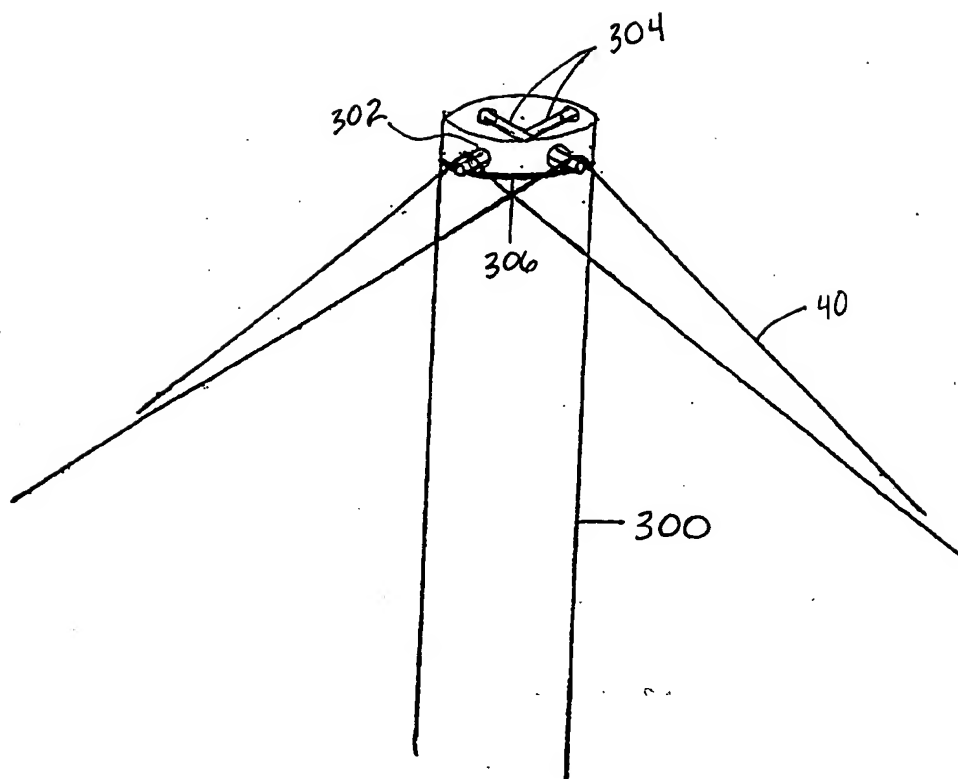
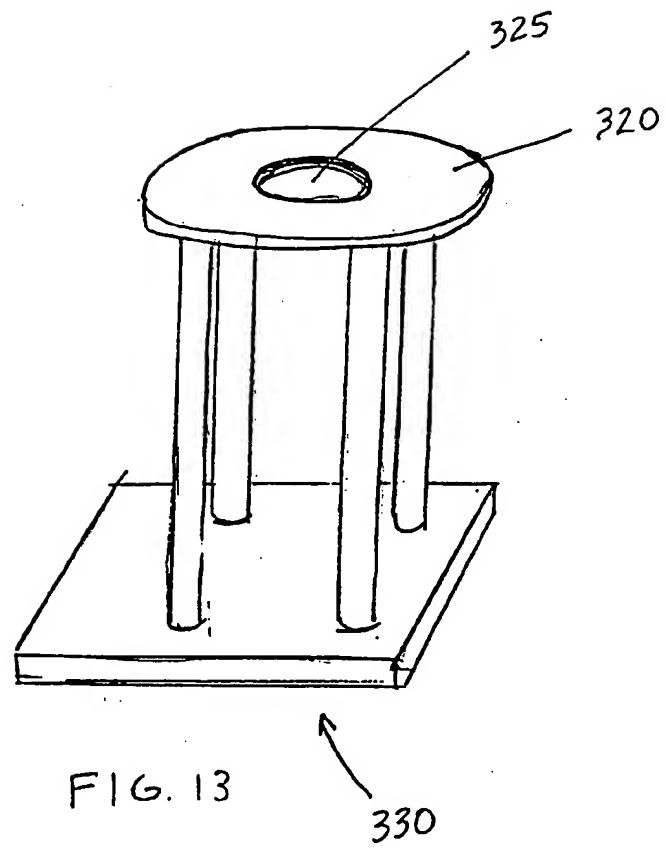
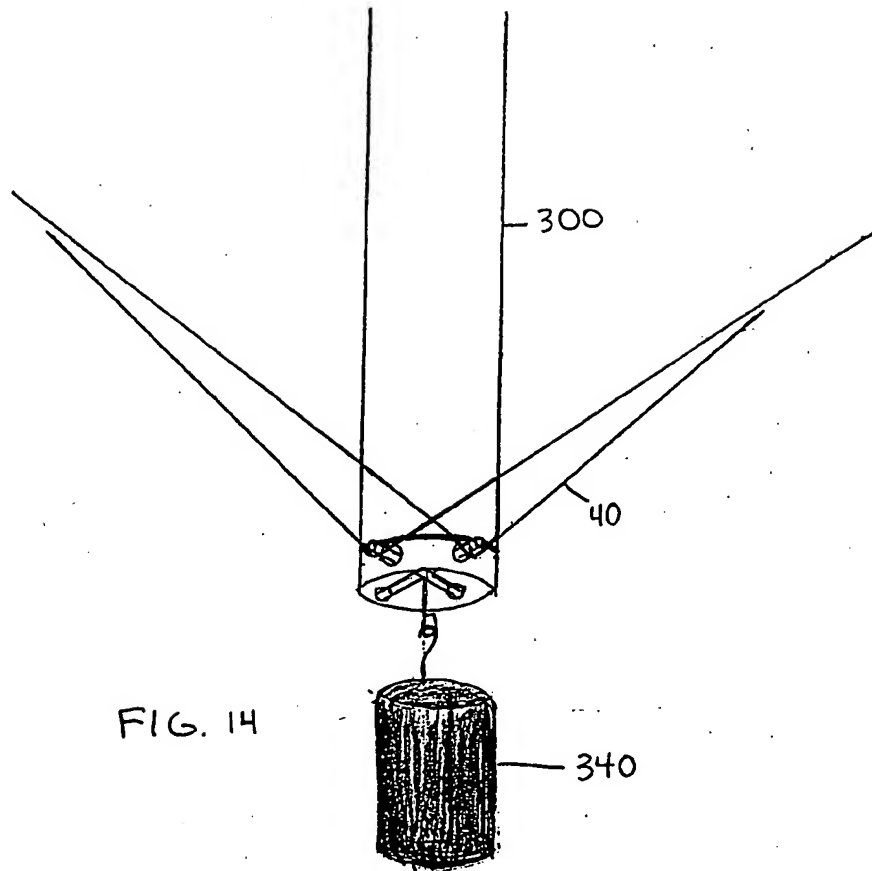


FIG. 12





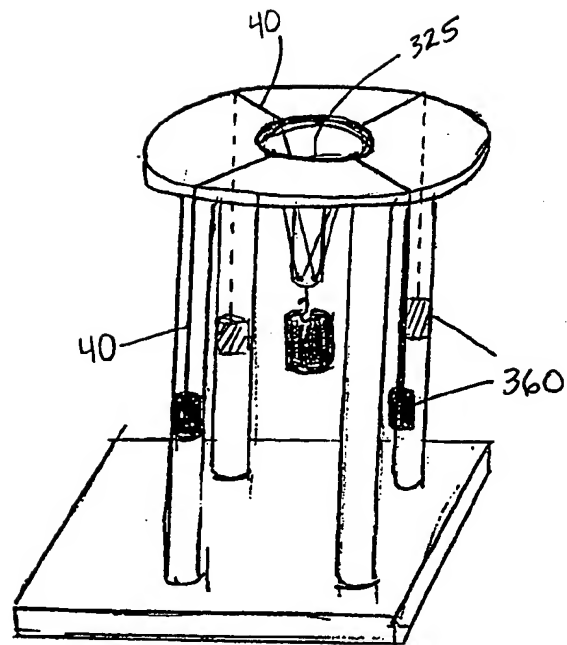


FIG. 15

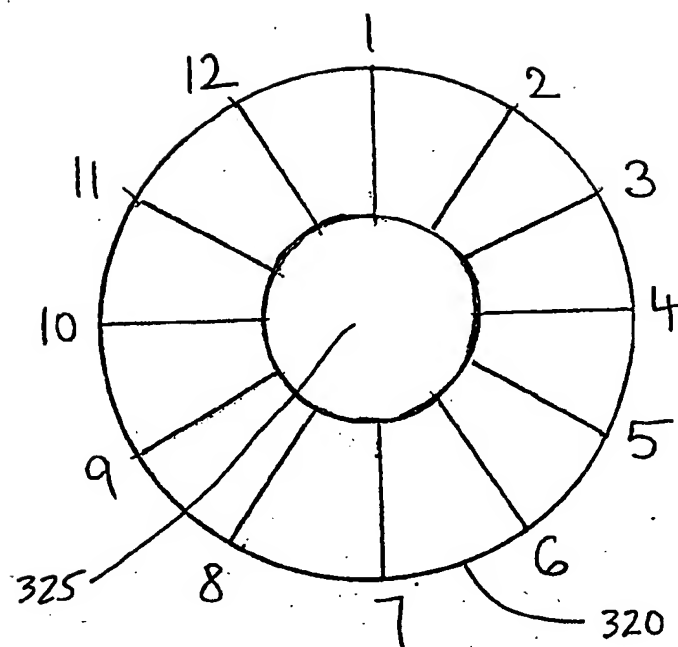
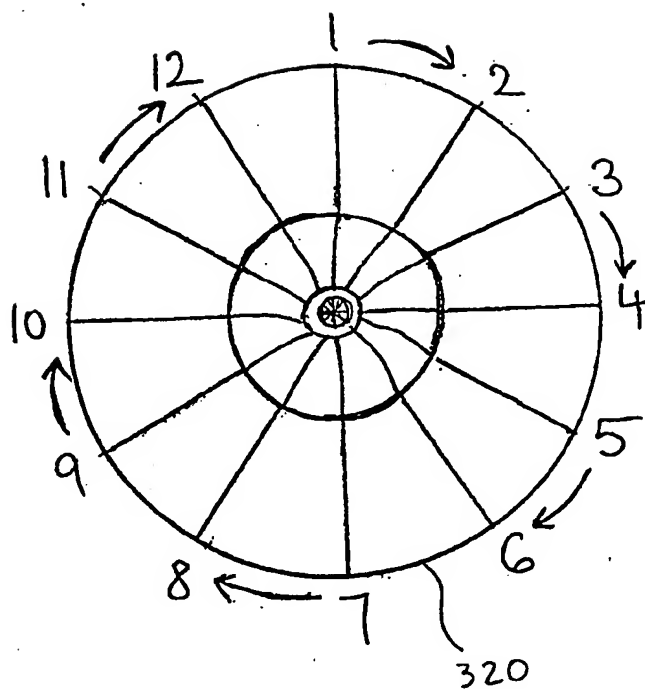
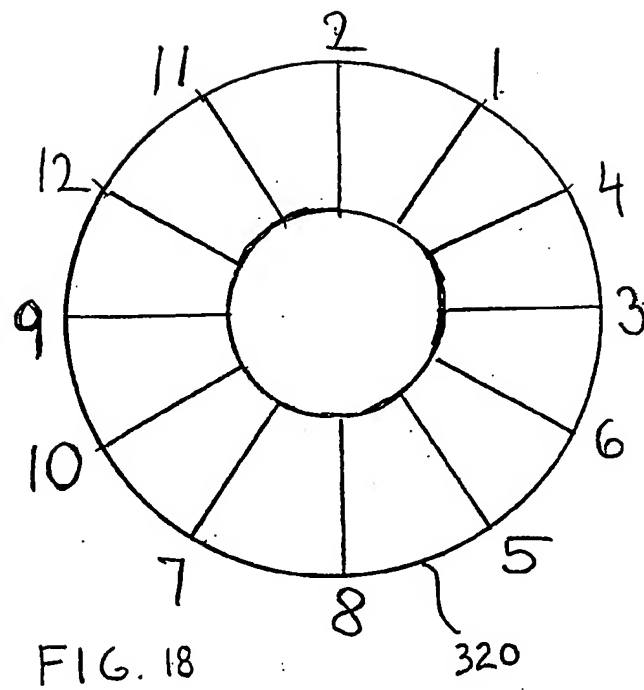


FIG. 16

FIG. 17





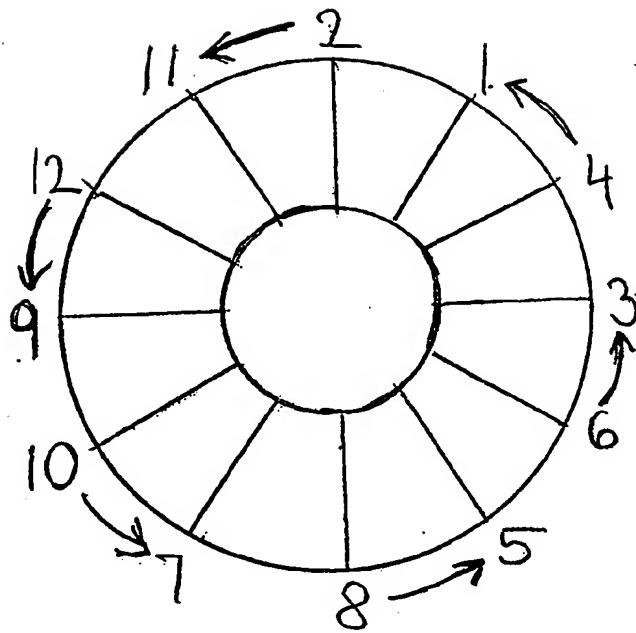
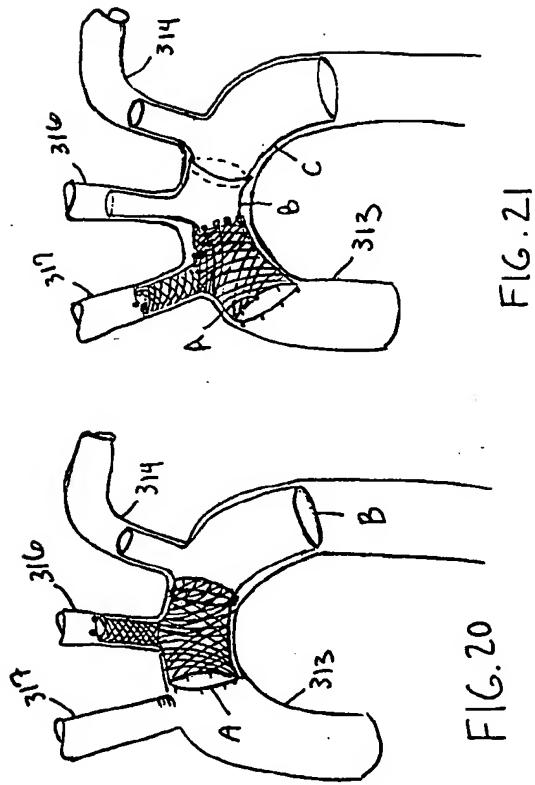


FIG. 19



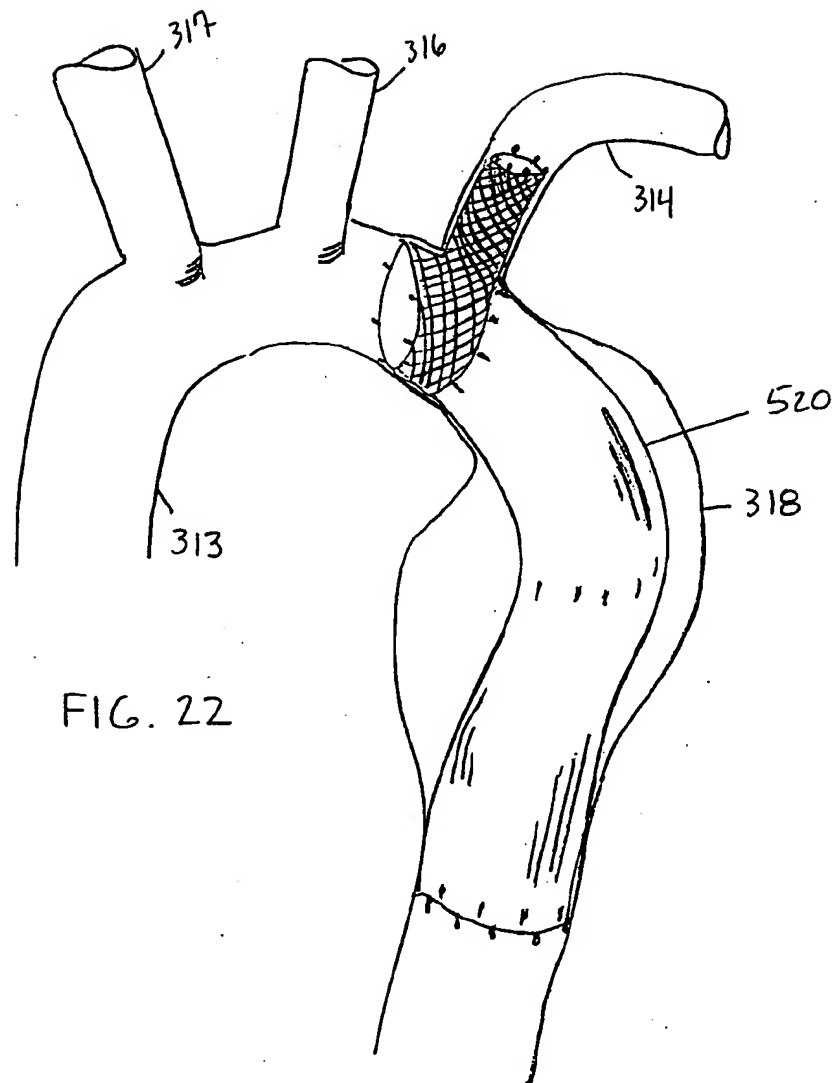


FIG. 22

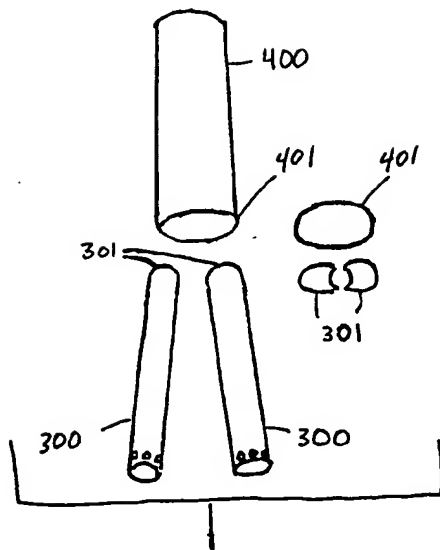


FIG. 23

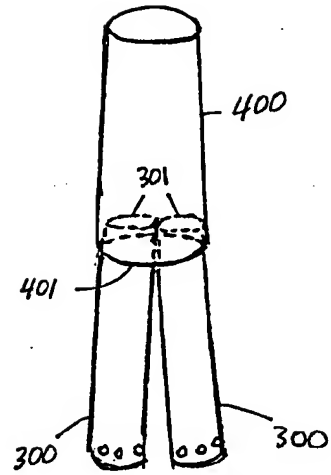


FIG. 24

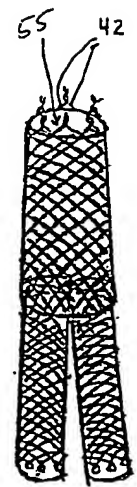
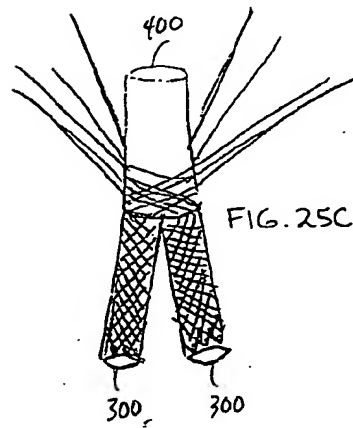
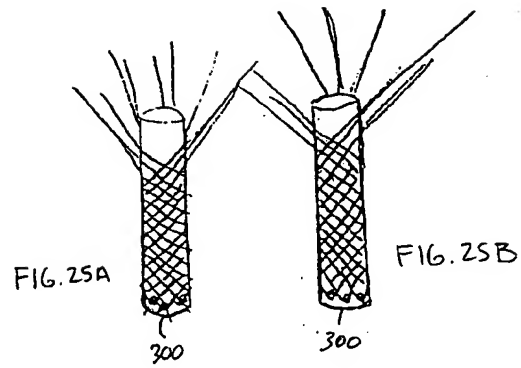


FIG. 26

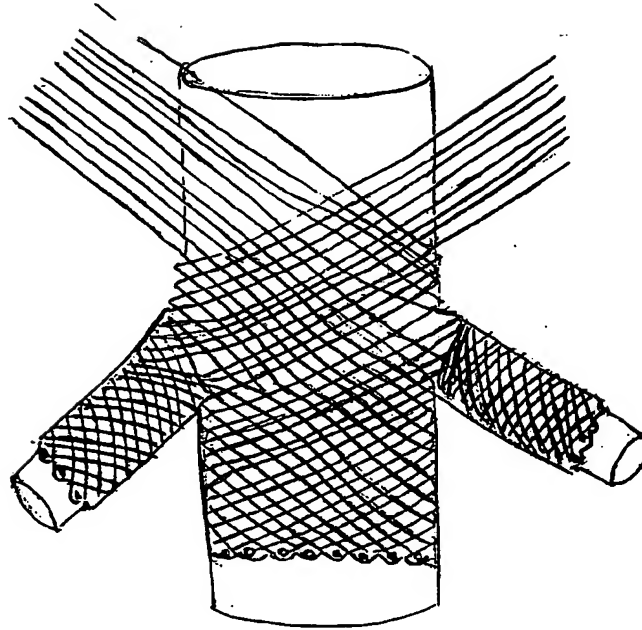


FIG. 27B

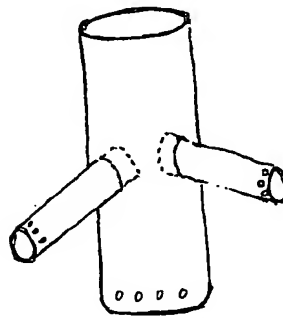


FIG. 27A

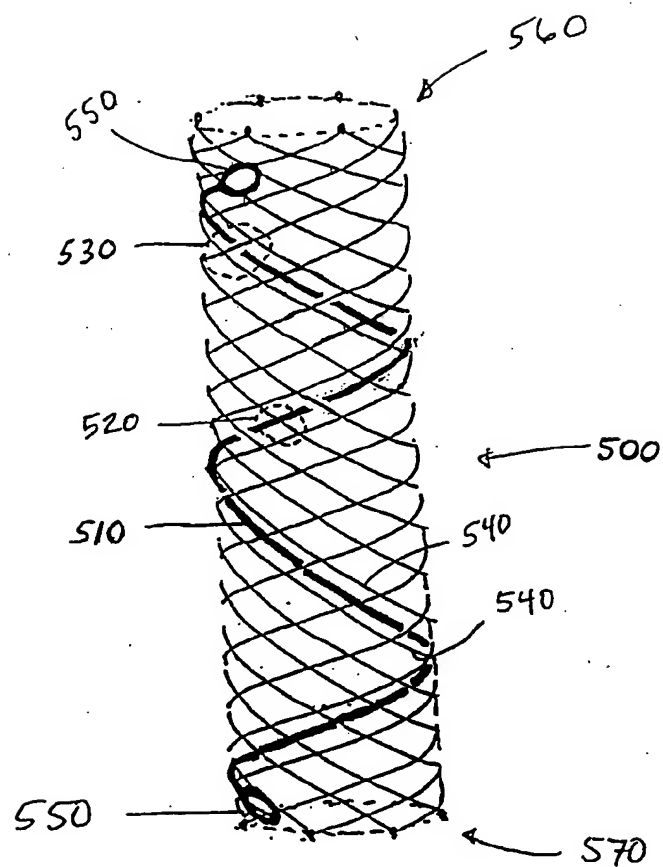


FIG. 28

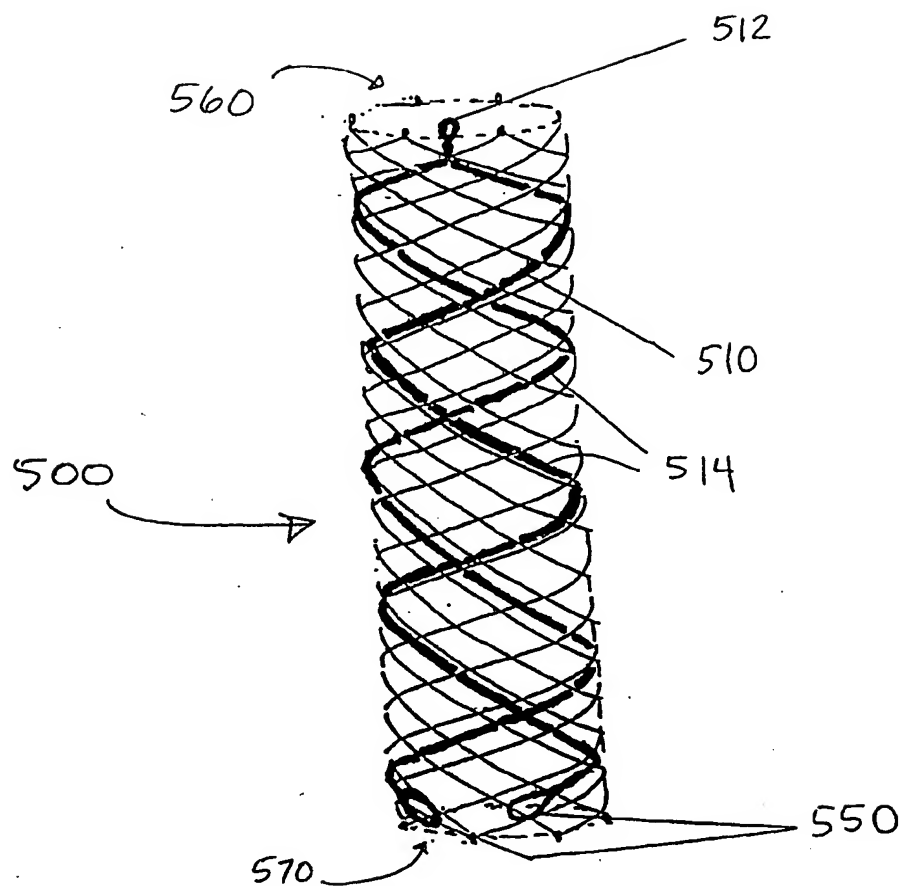


FIG. 29

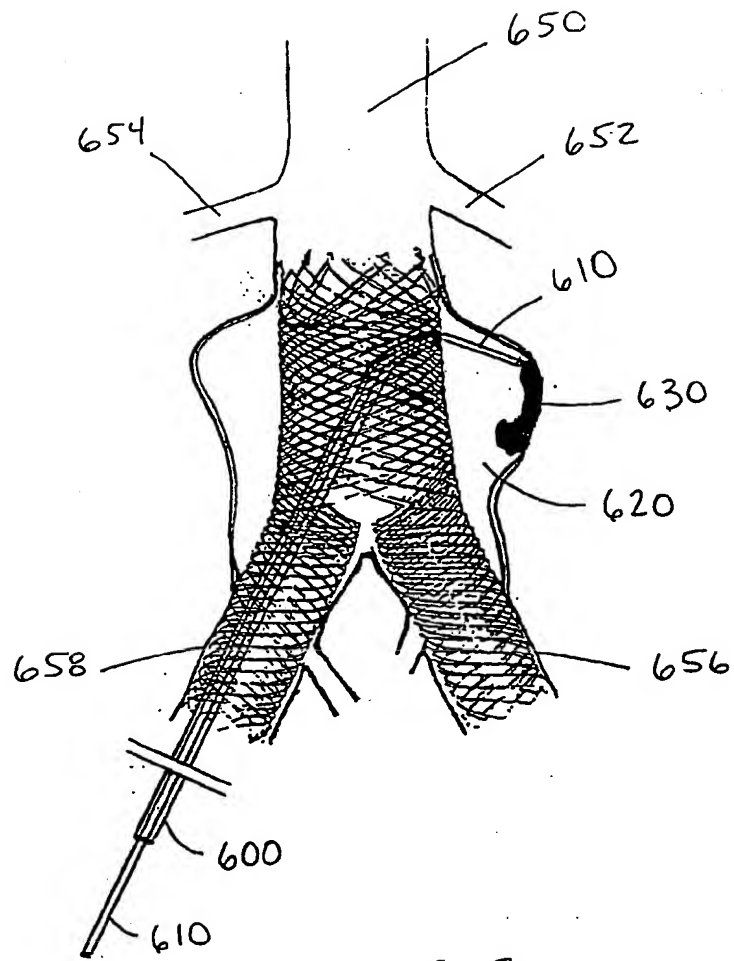


FIG. 30

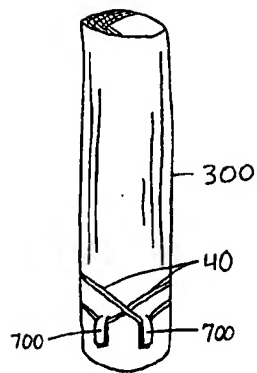


FIG. 31

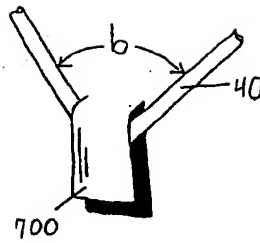


FIG. 32A

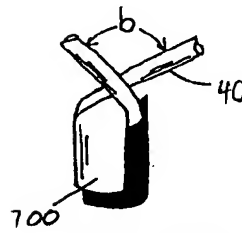


FIG. 32B

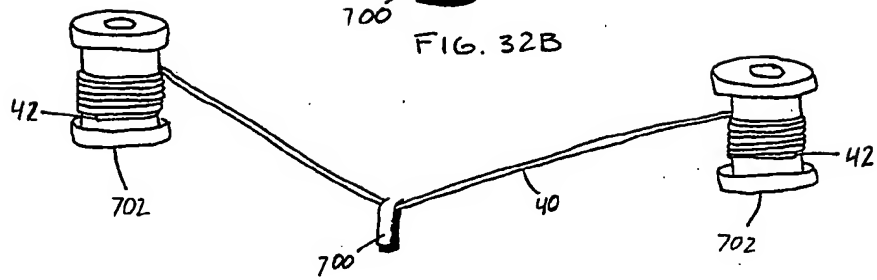


FIG. 33

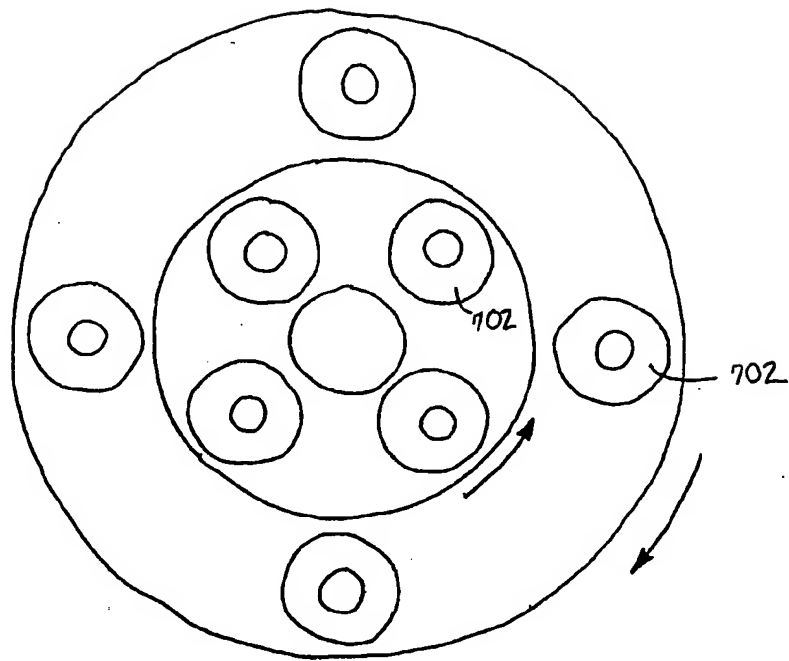
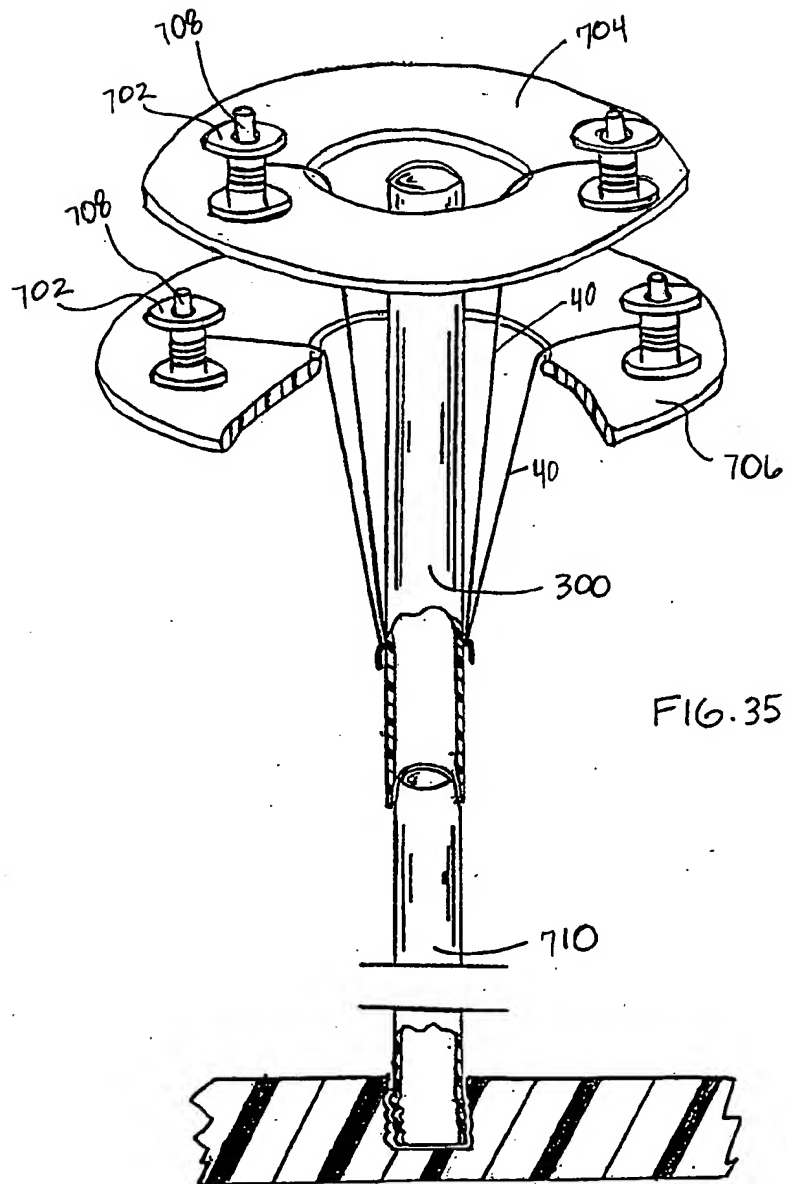


FIG. 34



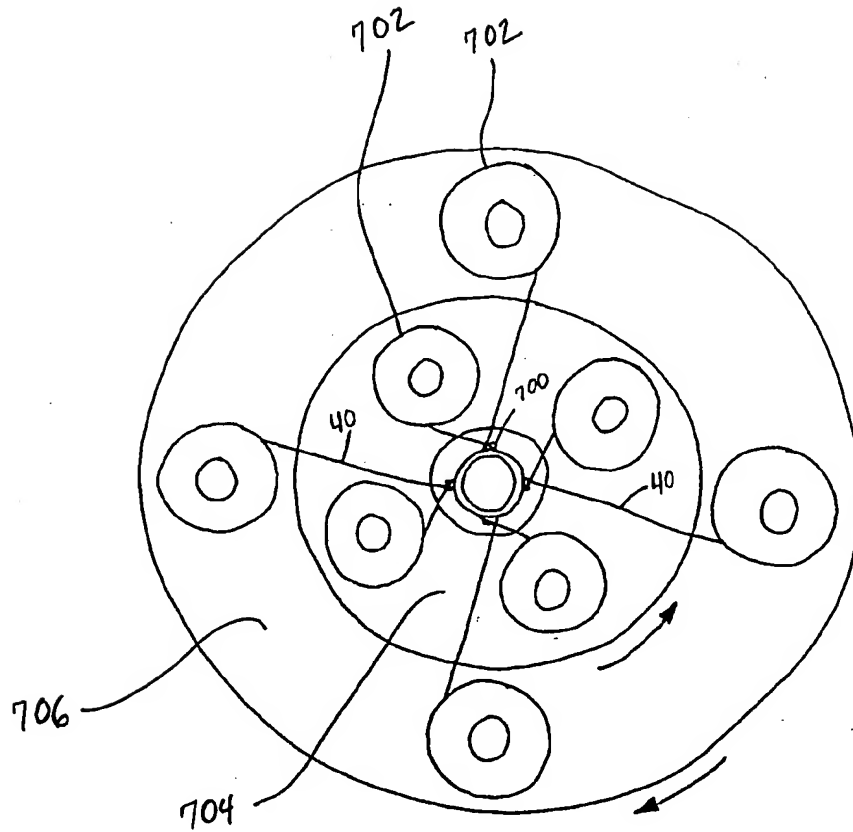


FIG. 36A

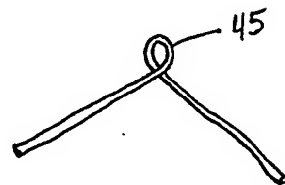


FIG. 36B

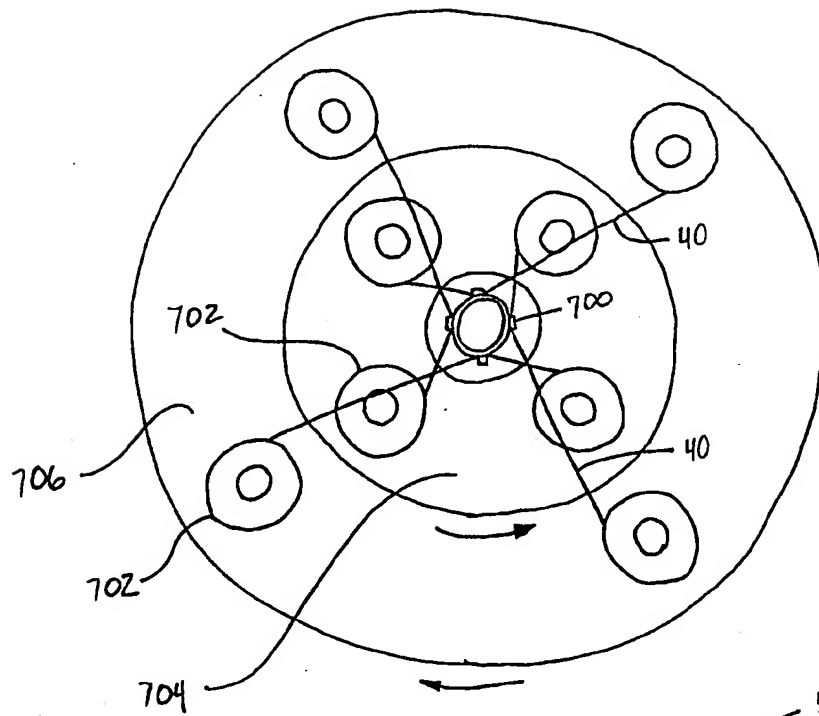


FIG. 37A

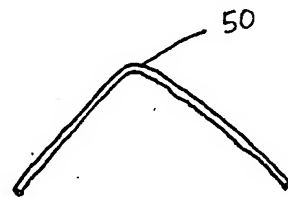


FIG. 37B

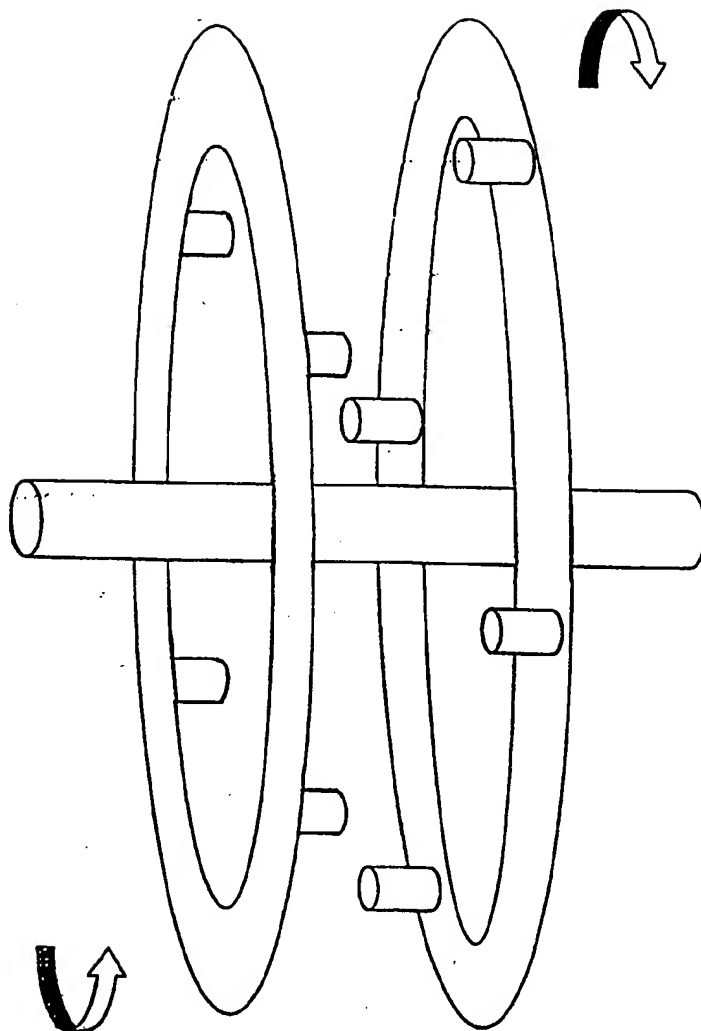


FIG. 38

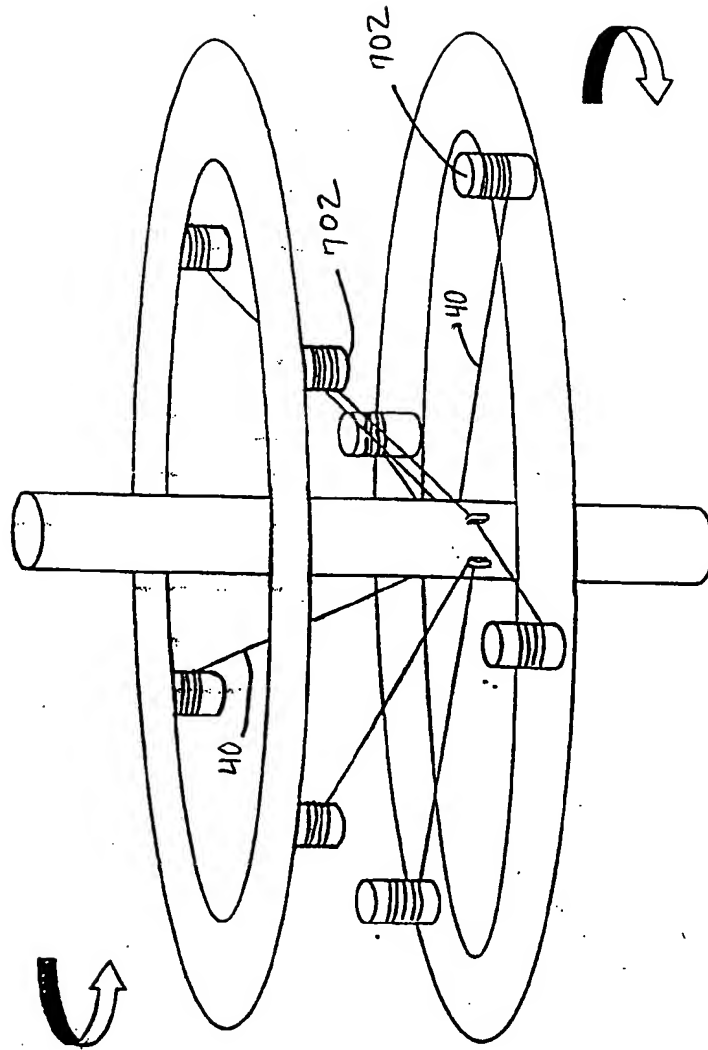
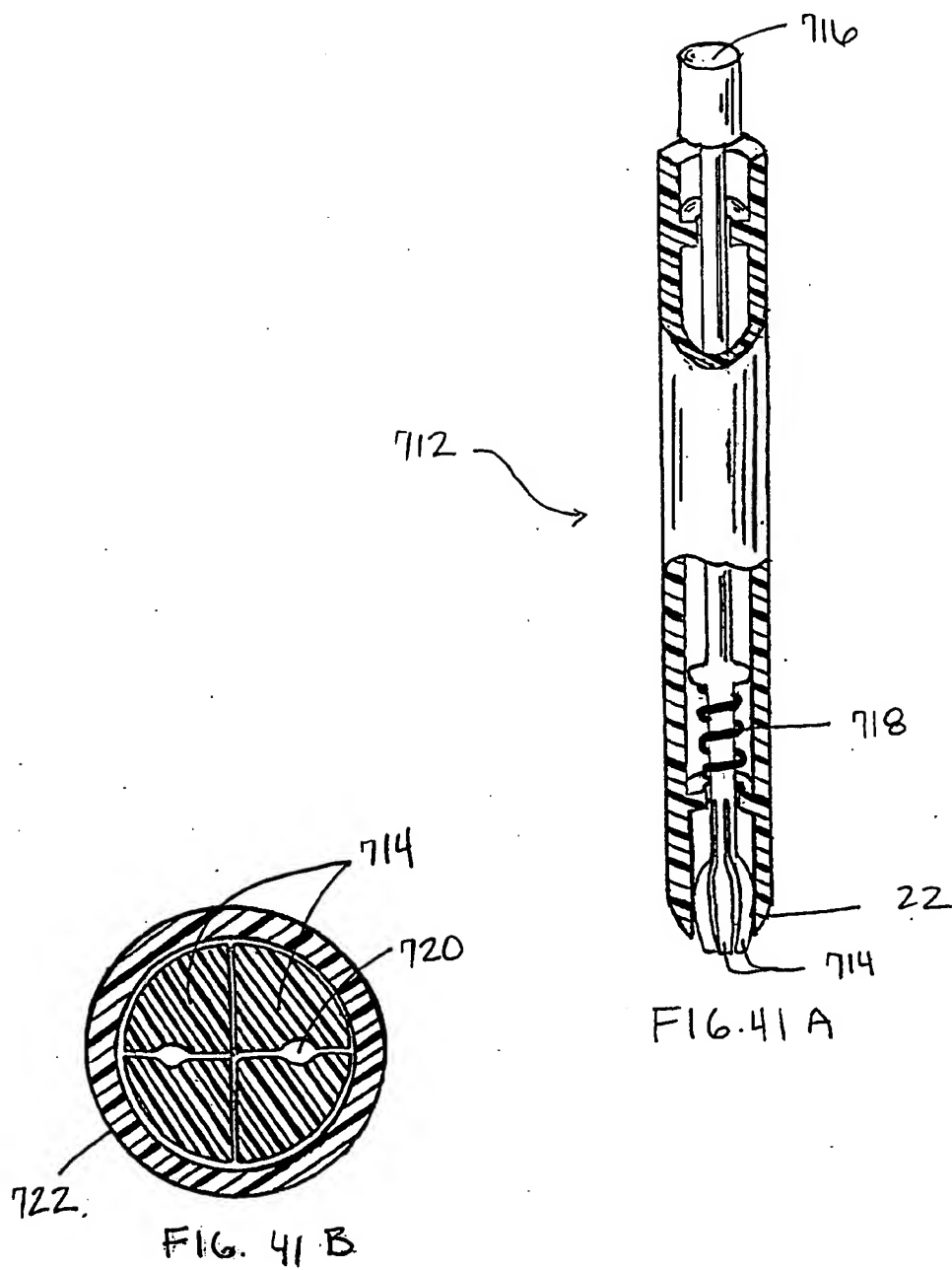


FIG. 39



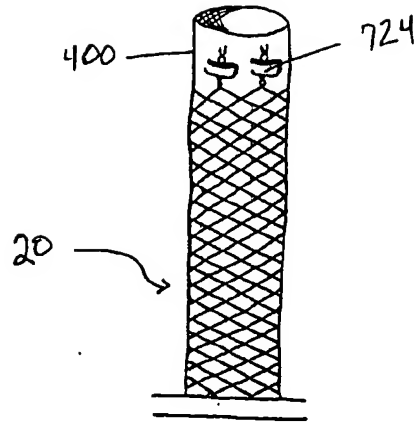


FIG. 42A

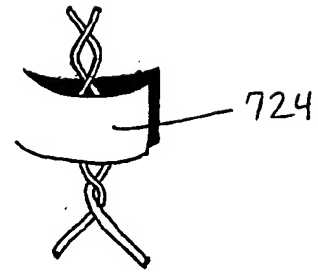


FIG. 42B



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification: A61F 2/06	A3	(11) International Publication Number: WO 00/44309 (43) International Publication Date: 03 August 2000 (03.08.2000)		
(21) International Application Number: PCT/US00/02582 (22) International Filing Date: 01 February 2000 (01.02.2000) (30) Priority Data: 60/118,185 01 February 1999 (01.02.1999) US 60/125,192 18 March 1999 (18.03.1999) US (60) Parent Application or Grant BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [/]; (). HYODOH, Hideki [/]; (). KONYA, Andras [/]; (). WRIGHT, Kenneth, C. [/]; (). GARRETT, Mark, T. ; ().	Published			
(54) Title: WOVEN BIFURCATED AND TRIFURCATED STENTS AND METHODS FOR MAKING THE SAME (54) Titre: PROTHESES ENDOVASCULAIRES TISSEES BIFURQUEES ET TRIFURQUEES ET LEURS PROCEDES DE FABRICATION				
(57) Abstract <p>Bifurcated and trifurcated woven stents (10) for insertion and delivery into a variety of anatomical structures, including the aortic-iliac bifurcation, the superior vena cava junction, and the inferior vena cava junction. The bifurcated stents (10) includes a first leg (30) formed from a first plurality of wires, a second leg (30) formed from a second plurality of wires (40), and a common body formed from the first and second pluralities of wires (40). The wires may be nitinol. Biodegradable filaments may also be utilized. The angles created between the crossed wires is preferably obtuse. The bifurcated stents (10) may be formed from as few as two wires. The stents may be formed using plain weaving effected either by hand or by machine.</p> (57) Abrégé <p>L'invention concerne des prothèses endovasculaires tissées bifurquées et trifurquées destinées à être implantées et transportées dans une variété de structures anatomiques, telles que la bifurcation aorto-iliaque, la jonction de la veine cave supérieure et la jonction de la veine cave inférieure. Les prothèses endovasculaires bifurquées présentent une première branche constituée d'une première pluralité de fils, une seconde branche constituée d'une seconde pluralité de fils et un corps commun constitué de la première et de la seconde pluralité de fils. Lesdits fils peuvent être en nitinol. On peut également utiliser des filaments biodégradables. Les angles créés entre les fils se croisant sont de préférence obtus. L'invention concerne également une variété de dispositifs de transport constitués de tubes de différentes tailles, certaines parties desdits tubes pouvant fonctionner de façon coaxiale les uns avec les autres. On peut former un prothèse endovasculaire bifurquée à partir de deux fils. On peut former les prothèses endovasculaires en utilisant la technique d'armature unie mise en oeuvre soit à la main, soit à la machine.</p>				

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
3 August 2000 (03.08.2000)

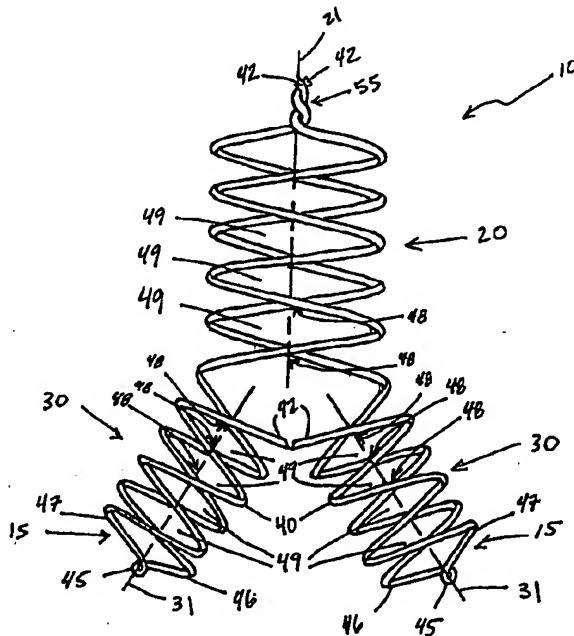
PCT

(10) International Publication Number
WO 00/44309 A3

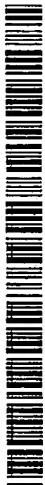
- (51) International Patent Classification: **A61F 2/06** (74) Agent: **GARRETT, Mark, T.**; Fulbright & Jaworski, Suite 2400, 600 Congress Avenue, Austin, TX 78701 (US).
- (21) International Application Number: **PCT/US00/02582**
- (22) International Filing Date: **1 February 2000 (01.02.2000)** (81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (25) Filing Language: **English**
- (26) Publication Language: **English**
- (30) Priority Data:
60/118,185 1 February 1999 (01.02.1999) US
60/125,192 18 March 1999 (18.03.1999) US
- (71) Applicant: **BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM [US/US]**; 201 West. 7th Street, Austin, TX 78701 (US).
- (72) Inventors: **HYODOH, Hideki**; Kawachi, Tochigi (JP). **KONYA, Andras**; 550 N. Bracswood #256, Houston, TX 77096 (US). **WRIGHT, Kenneth, C.**; 1802 Haver, Houston, TX 77006-2414 (US).
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).
- Published:
— With international search report.

[Continued on next page]

(54) Title: **WOVEN BIFURCATED AND TRIFURCATED STENTS AND METHODS FOR MAKING THE SAME**



(57) Abstract: Bifurcated and trifurcated woven stents (10) for insertion and delivery into a variety of anatomical structures, including the aortic-iliac bifurcation, the superior vena cava junction, and the inferior vena cava junction. The bifurcated stents (10) includes a first leg (30) formed from a first plurality of wires, a second leg (30) formed from a second plurality of wires (40), and a common body formed from the first and second pluralities of wires (40). The wires may be nitinol. Biodegradable filaments may also be utilized. The angles created between the crossed wires is preferably obtuse. The bifurcated stents (10) may be formed from as few as two wires. The stents may be formed using plain weaving effected either by hand or by machine.



WO 00/44309 A3

WO 00/44309 A3



(88) Date of publication of the international search report:
30 November 2000

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INTERNATIONAL SEARCH REPORT

Int. J. Appl. No.
PCT/US 00/02582**A. CLASSIFICATION OF SUBJECT MATTER**
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHEDMinimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 197 03 482 A (STRECKER ERNST PETER PROF DR M) 6 August 1998 (1998-08-06)	1,2,7, 14,15, 26,29
A	column 10, line 2 -column 12, line 4; figures 1-12	3,4,17, 18,20
X	WO 98 19630 A (VASCULAR SCIENCE INC) 14 May 1998 (1998-05-14)	14,15
A	page 8, line 12 -page 10, line 26; figures 1,2 page 12, line 23 -page 13, line 19; figures 9-12	1,2,7, 17,18, 20,26, 29,30,33
	-/-	



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Patent family members are listed in annex.

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Date of the actual completion of the international search

19 July 2000

Date of mailing of the international search report

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Levert, C

INTERNATIONAL SEARCH REPORT

Int. Patent Application No.

PCT/US 00/02582

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 11847 A (WHAYNE JAMES G; FLEISCHMAN SID D; HOUSER RUSSELL A) 26 March 1998 (1998-03-26) page 9, line 26 -page 11, line 12; figure 5 page 18, line 21 - line 22; figure 34	1,2,10, 11, 13-15, 17,18, 23,24, 26,29
A	EP 0 804 909 A (SCHNEIDER USA INC) 5 November 1997 (1997-11-05) column 7, line 33 -column 13, line 4; figures 1-10 column 17, line 28 - line 33	1-5, 14-18, 26,29, 30,33,34
A	WO 98 46168 A (SCHNEIDER USA INC) 22 October 1998 (1998-10-22) page 8, line 4 - line 19; figures 3,4 page 11, line 14 -page 13, line 2; figures 15,16 page 15, line 3 - line 10; figure 20	1,2,9, 10, 12-15, 17,18, 22,23, 25,26, 29,30, 33,36
A	WO 97 16133 A (BIOCOMPATIBLES LTD; TAYLOR A S; STRATFORD P W; YIANNI Y; WOODROFFE M J) 9 May 1997 (1997-05-09) page 9, line 29 -page 10, line 4 page 19, line 11 -page 24, line 34; figures 1-5	1-6,9, 14,15, 17-19, 22,30, 33,34,36
A	US 5 769 882 A (FOGARTY ET AL) 23 June 1998 (1998-06-23) column 9, line 67 -column 10, line 19; figure 15	17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/02582

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 19703482 A	06-08-1998	AU 6390398 A WO 9833454 A EP 0964659 A	25-08-1998 06-08-1998 22-12-1999
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